

US3662101 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:23:56

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US3662101

Form: Participant Creation

Data signed: (b) (4) 18 Mar 2021 22:06:34

Generated On: 10 Jun 2021 09:23:56

Participant ID

US3662101

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

US3662101

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Mar 2021 22:06:35

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Date of Informed Consent (dd MMM yyyy)	16 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Mar 2021 22:06:35

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Mar 2021 22:06:35

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Mar 2021 22:06:35

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Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	01 JUL 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Condition	TYPE II DIABETES MELLITUS
Start date (dd MMM yyyy)	01 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Condition	MUSCLE PAIN
Start date (dd MMM yyyy)	01 JUL 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Condition	HYPERLIPIDEMIA, UNSPECIFIED
Start date (dd MMM yyyy)	01 JUL 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Condition	HYPERTENSION NEC
Start date (dd MMM yyyy)	01 JUL 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	01 JUL 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:03 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:03
Height (<i>xxx.x</i>)	177.8 cm
Weight (<i>xxx.x</i>)	87 kg
BMI (<i>xxx.x</i>)	27.52046 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:06:35

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Mar 2021 22:06:35

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Mar 2021 22:06:35

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

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

What was the participant's randomization number? 190922

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

>=18 and <65 years and at risk ☐

>=65 years ☒

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

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

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

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

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

Liver Disease Yes ☐
No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐
No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	09:03 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:03
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:17
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 09:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

09:10 (24 HR)

Collection date and time (derived)

16 SEP 2020 09:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:05	16 SEP 2020 09:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 10:19

PC Open Date & Time

16 SEP 2020 10:05

PC Close Date & Time

16 SEP 2020 12:35

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	16 SEP 2020 13:57
PC Open Date & Time	16 SEP 2020 13:30
PC Close Date & Time	17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 19:23

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 20:43

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 20:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 18:51

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 19:37

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 18:25

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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

16 SEP 2020 10:19

PC Open Date & Time

16 SEP 2020 10:05

PC Close Date & Time

16 SEP 2020 12:35

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

16 SEP 2020 13:58

PC Open Date & Time

16 SEP 2020 13:30

PC Close Date & Time

17 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

3

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

17 SEP 2020 19:24

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:44

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 20:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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

20 SEP 2020 18:52

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 19:38

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 18:26

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:20
PC Open Date & Time	16 SEP 2020 10:05
PC Close Date & Time	16 SEP 2020 12:35

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 13:59
PC Open Date & Time	16 SEP 2020 13:30
PC Close Date & Time	17 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	17 SEP 2020 19:25
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	18 SEP 2020 20:45
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 ☒

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EAB) (1725)

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US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	19 SEP 2020 20:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	20 SEP 2020 18:52
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

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 ☒

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EAB) (1725)

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	21 SEP 2020 19:39
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2643

EAB) (1725)

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	22 SEP 2020 18:27
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3662101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	07:56 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 07:56
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:19
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3662101

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 OCT 2020

What was the treatment time? (00:00-23:59) 08:46 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 08:46

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

What was the frequency of the study treatment dosing? ONCE

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

US3662101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

08:15 (24 HR)

Collection date and time (derived)

14 OCT 2020 08:15

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:10	14 OCT 2020 08:10
Nasopharyngeal Swab 2	No		

US3662101

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 09:21

PC Open Date & Time

14 OCT 2020 09:06

PC Close Date & Time

14 OCT 2020 11:36

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

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

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

PC Time Stamp 14 OCT 2020 17:35

PC Open Date & Time 14 OCT 2020 12:31

PC Close Date & Time 15 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	99.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

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

PC Time Stamp	15 OCT 2020 17:45
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 18:41

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

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

PC Time Stamp	17 OCT 2020 19:50
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 17:08

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 19 OCT 2020 17:01

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 19:17

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 09:21

PC Open Date & Time

14 OCT 2020 09:06

PC Close Date & Time

14 OCT 2020 11:36

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 17:35

PC Open Date & Time

14 OCT 2020 12:31

PC Close Date & Time

15 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 17:46

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 18:42

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

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

17 OCT 2020 19:50

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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

18 OCT 2020 17:08

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 17:02

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 19:18

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 09:22
PC Open Date & Time	14 OCT 2020 09:06
PC Close Date & Time	14 OCT 2020 11:36

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 17:38
PC Open Date & Time	14 OCT 2020 12:31
PC Close Date & Time	15 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	15 OCT 2020 17:47
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	16 OCT 2020 18:43
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 ☒

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EAB) (1725)

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	17 OCT 2020 19:52
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	18 OCT 2020 17:10
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	19 OCT 2020 17:02
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

Yes ☐	
PC Time stamp	20 OCT 2020 19:19
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3662101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 08:10
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662101

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3662101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

08:30 (24 HR)

Collection date and time (derived)

12 NOV 2020 08:30

US3662101

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 13:03:06

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ 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 NOV 2020 05:25:32
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 08:05:46
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 10:24:59

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 10:41:39
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐
Have 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):	
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 ☐
Date and time of submission	18 DEC 2020 09:09:25
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

25 DEC 2020 07:36:58

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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	01 JAN 2021 10:14:58
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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	08 JAN 2021 09:52:39
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 06:48:46
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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	22 JAN 2021 09:34:54
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

30 JAN 2021 12:56:52

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

07 FEB 2021 12:01:48

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 05:01:17
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐
Have 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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	19 FEB 2021 07:09:53
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐
Have 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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	26 FEB 2021 14:45:04
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

05 MAR 2021 06:43:18

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 12:31:24

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 09:48:36

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 09:40:06

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

04 APR 2021 12:01:11

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

10 APR 2021 18:57:08

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 07:54:31

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 05:21:52
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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	30 APR 2021 06:30:49
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 236

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 271

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

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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°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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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27 JUL 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

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30 NOV 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

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14 DEC 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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29 MAR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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08 APR 2022 00:01

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12 APR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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19 APR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

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26 APR 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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03 MAY 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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10 MAY 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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20 MAY 2022 00:01

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24 MAY 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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27 MAY 2022 00:01

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31 MAY 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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17 JUN 2022 00:01

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21 JUN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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19 JUL 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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09 AUG 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

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30 AUG 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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06 SEP 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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09 SEP 2022 00:01

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13 SEP 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐ 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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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23 SEP 2022 00:01

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27 SEP 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 747

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

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

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

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

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

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

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3662101

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:23:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 07:36:05

US3662101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3662101

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662101

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3662101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3662101

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

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.

US3662101

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3662101

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3662101

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:23:56

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3662101

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:23:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3662101

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

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	12 JAN 2021

Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒

Folder OID	UNBLND_DECIDE

US3662101

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 19:05:11

Generated On: 10 Jun 2021 09:23:56

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3662101

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 22:06:35

Generated On: 10 Jun 2021 09:23:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

12 JAN 2021 11:00

US3662101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Mar 2021 22:06:34

Generated On: 10 Jun 2021 09:23:56

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	10:05
Collection Date and Time (derived)	12 JAN 2021 10:05

US3662101

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Mar 2021 22:06:34

Generated On: 10 Jun 2021 09:23:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

AEID	USA-US088-2021-MRNA-1273-P30 1000010
Adverse event	MALIGNANT NEOPLASM OF PAROTID GLAND STAGE IVA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	17 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	True
Hospital Admission Date (dd MMM yyyy)	08 APR 2021
Hospital Discharge Date (dd MMM yyyy)	11 APR 2021
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	324 of 2643

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

		MALE WITH A CANCER OF THE PAROTID GLAND, S/P PAROTIDECTOMY, LEFT-SIDED NECK DISSECTION, AND SUBMENTAL ISLAND FLAP FOR LEFT-SIDED MALIGNANT NECK MASS, PARTIAL L 7TH NERVE RESECTION RESULTING IN EXPECTED PALSY DISPOSITION: SICU FOR ELEVATED BP, LIKELY FLOOR IN AM CARDIOVASCULAR - HOME BLOOD PRESSURE MEDS RESTARTED - HOLDING ANTICOAGULATION - ARTERIAL LINE PER SICU
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)		1

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

AEID	
Adverse event	HYPOMAGNESEMIA
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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

AEID	
Adverse event	LEFT FACIAL NERVE PALSY SECONDARY TO SURGICAL PROCEDURE
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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (4)

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

AEID	
Adverse event	ELEVATED BLOOD PRESSURE POST SURGERY
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)	10 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	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

AEID	
Adverse event	BRADYCARDIA DURING SURGERY
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	

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Form: Adverse Events (6)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Mar 2021 22:06:34

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication CIALIS

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication TESTOSTERONE GEL 1.62 %

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 20.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication JANUMET

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 50-1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2015	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	21 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SORENESS

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication EZETIMIBE

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2008	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2003	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication ATORVASTATINE CALCIUM

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2003	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2003	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 17 OCT 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	7 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication METAFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication EPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication EPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication GLYCOPYRROLATE

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 0.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication EPINEPHRINE HCL COMB;
LIDOCAINE HCL 1%-1:100,000

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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Name of Medication REMIFENTANIL

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication EPINEPHRINE HCL

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication SUCCINYLCHOLINE CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 125

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication LIDOCAINE HCL

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication MIDAZOLAM HCL

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication INCISIONAL BIOPSY

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication ULTRAM

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE FOR LEFT
PAROTIDECTOMY, LEFT NECK
DISSECTION SUBMENTAL FLAP
NERVE RESECTION AND NERVE
GRAFT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE FOR LEFT
PAROTIDECTOMY, LEFT NECK
DISSECTION SUBMENTAL FLAP
NERVE RESECTION AND NERVE
GRAFT

Dose per administration 975

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	11 APR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication SENNA CONCENTRATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PREVENTION

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	11 APR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication BACITRACIN ZINC; COMB;
POLYMYXIN B SULFATE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE

Dose per administration 1000/500

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 13:41:25

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	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		11 APR 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication OXYCODONE HCL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE FOR LEFT
PAROTIDECTOMY, LEFT NECK
DISSECTION SUBMENTAL FLAP
NERVE RESECTION AND NERVE
GRAFT

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

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	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE FOR LEFT
PAROTIDECTOMY, LEFT NECK
DISSECTION SUBMENTAL FLAP
NERVE RESECTION AND NERVE
GRAFT

Dose per administration 400

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☒	
	No ☐	
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication HYDROMORPHONE HCL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE FOR LEFT
PAROTIDECTOMY, LEFT NECK
DISSECTION SUBMENTAL FLAP
NERVE RESECTION AND NERVE
GRAFT

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	9 APR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication HYDRALAZINE HCL

Prophylaxis Yes ☐
No ☒

Indication ELEVATED BP POST SURGERY

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

EVERY 4-6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy) 9 APR 2021		
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication BLOOD CLOT PREVENTION

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	11 APR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication EPINEPHRINE HCL

Prophylaxis Yes ☐
No ☒

Indication BRADYCARDIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy) 8 APR 2021		
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication HYPOMAGNESEMIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	9 APR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication INSULIN LISPRO; HUMALOG

Prophylaxis Yes ☐
No ☒

Indication TYPE 3 DIABETES MELLITUS

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	11 APR 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE FOR LEFT
PAROTIDECTOMY, LEFT NECK
DISSECTION SUBMENTAL FLAP
NERVE RESECTION AND NERVE
GRAFT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Subcutaneous	☐
	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes ☒	
	No ☐	
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

Name of Medication DOCUSATE SODIUM; COMB;
SENNA CONCENTRATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PREVENTION

Dose per administration 8.6/50

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 13:41:25

Generated On: 10 Jun 2021 09:23:56

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Mar 2021 22:06:34

Generated On: 10 Jun 2021 09:23:56

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 19:05:11

Generated On: 10 Jun 2021 09:23:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 JAN 2021	CT LUNG SCREENING	Other	SCREENING, HISTORY OF SMOKING
11 FEB 2021	ECHO STRESS TEST	Medical History	
25 FEB 2021	CT NECK WITH CONTRAST	Adverse Event	
5 MAR 2021	FNA NEEDLE BIOPSY	Adverse Event	
11 MAR 2021	NM DET CT SKULL THIGH	Adverse Event	
16 MAR 2021	INCISIONAL BIOPSY OF NECK MASS	Adverse Event	
11 MAR 2021	MRI ORBIT FACE NECK W/WITHOUT CONTRAST	Adverse Event	
11 MAR 2021	MRI HEAD W/WITHOUT CONTRAST	Adverse Event	
08 APR 2021	LEFT PAROTIDECTOMY LEFT NECK DISSECTION SUBMENTAL FLAP NERVE RESECTION AND NERVE GRAFT.	Adverse Event	

US3662101

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:23:56

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

US3662101

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:23:56

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 ☐

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 13:41:26

Generated On: 10 Jun 2021 09:23:56

SAEID	USA-US088-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
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)	2

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 13:41:26

Generated On: 10 Jun 2021 09:23:56

SAEID	USA-US088-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
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)	2
Date of submission (Pre-filled from custom function)	12/APR/2021 06:08
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

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 13:41:26

Generated On: 10 Jun 2021 09:23:56

SAEID	USA-US088-2021-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
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)	2
Date of submission (Pre-filled from custom function)	19/APR/2021 15:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3662101 (Prod: Cincinnati CRS)

US3662101

Form: Participant Creation

Generated On: 10 Jun 2021 09:23:56

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'US3662101'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 12:39:24

US3662101

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:03:49

US3662101

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 12:39:25

US3662101

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[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 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	17 Sep 2020 14:03:49

US3662101

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'SCRN'	System	17 Sep 2020 14:03:49

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 12:39:26

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '65'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'YEARS'	System	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '65'	System	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Male (M)'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '1'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:23:56

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:05:07

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'Sep 2020'	System	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '2020'	System	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Amendment 3 (3)'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:12:37

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 12:39:25

US3662101

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:23:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '1'	System	16 Sep 2020 13:12:41

US3662101

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:23:56

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:12:41

US3662101

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:23:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:05:46

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 14:07:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 14:07:33
Data point term sent to Coder	System	17 Sep 2020 14:06:59
User entered 'ENLARGED PROSTATE'	Brenda Miller (b) (4)	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2019'	Brenda Miller (b) (4)	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'Jul 2019'	System	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '2019'	System	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:23:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:06:16

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Sep 2020 14:07:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 14:07:34
Data point term sent to Coder	System	17 Sep 2020 14:07:00
User entered 'TYPE II DIABETES MELLITUS'	Brenda Miller (b) (4)	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2015'	Brenda Miller (b) (4)	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'Jul 2015'	System	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '2015'	System	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:23:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:06:39

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 14:08:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 14:08:38
Data point term sent to Coder	System	17 Sep 2020 14:08:02
User entered 'MUSCLE PAIN'	Brenda Miller (b) (4)	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2010'	Brenda Miller (b) (4)	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'Jul 2010'	System	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '2010'	System	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:23:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:07:06

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Sep 2020 14:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 14:08:39
Data point term sent to Coder	System	17 Sep 2020 14:08:01
User entered 'HYPERLIPIDEMIA, UNSPECIFIED'	Brenda Miller (b) (4)	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2003'	Brenda Miller (b) (4)	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'Jul 2003'	System	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '2003'	System	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:23:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:07:26

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Sep 2020 14:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 14:08:39
Data point term sent to Coder	System	17 Sep 2020 14:08:04
User entered 'HYPERTENSION NEC'	Brenda Miller (b) (4)	17 Sep 2020 14:07:44
	(b) (4)	

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2003'	Brenda Miller (b) (4)	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'Jul 2003'	System	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '2003'	System	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:23:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:07:44

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	23 Sep 2020 17:13:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Sep 2020 17:13:48
Data point term sent to Coder	System	23 Sep 2020 17:13:14
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY 2) UNSPECIFIED ANGINA PECTORIS' (Site from System).	System	23 Sep 2020 17:12:59
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY 2) UNSPECIFIED ANGINA PECTORIS' answered with 'resolved' (Site from System).	michelle saemann (b) (4)	23 Sep 2020 17:12:59
User entered 'Coronary artery disease' reason for change: Data Entry Error	michelle saemann (b) (4)	23 Sep 2020 17:12:53
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY 2) UNSPECIFIED ANGINA PECTORIS' (Site from System).	Coder Import (b) (4)	23 Sep 2020 07:02:43
Data point term sent to Coder	System	17 Sep 2020 14:12:14
User entered 'ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY WITH UNSPECIFIED ANGINA PECTORIS'	Brenda Miller (b) (4)	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2003'	Brenda Miller (b) (4)	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'Jul 2003'	System	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '2003'	System	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:23:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	17 Sep 2020 14:11:39

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '09:03'	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '16 Sep 2020 09:03'	System	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '177.8' cm	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:12:45
DataPoint set to visible.	(b) (4) System	16 Sep 2020 13:12:41

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '87' kg	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:12:45
DataPoint set to visible.	(b) (4) System	16 Sep 2020 13:12:41

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '27.52046'	System	17 Sep 2020 14:12:45
DataPoint set to visible.	System	16 Sep 2020 13:12:41

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'kg/m2'	System	17 Sep 2020 14:12:45
DataPoint set to visible.	System	16 Sep 2020 13:12:41

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'bpm'	System	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'breaths/min'	System	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'mmHg'	System	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'mmHg'	System	17 Sep 2020 14:12:45

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54

US3662101

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54

US3662101

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:13:18

US3662101

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	Brenda Miller (b) (4)	17 Sep 2020 14:13:18

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '1'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:23:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:14:36

US3662101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:15:06

US3662101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	Brenda Miller (b) (4)	17 Sep 2020 14:15:06

US3662101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[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 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	17 Sep 2020 14:15:06

US3662101

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'VISIT1'	System	17 Sep 2020 14:15:06

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:09:28

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '190922'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:09:28

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:09:28

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

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 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) michelle saemann (b) (4)	17 Sep 2020 18:38:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

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 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	17 Sep 2020 18:38:21

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) michelle saemann (b) (4)	17 Sep 2020 18:38:21

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	17 Sep 2020 18:38:21

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) michelle saemann (b) (4)	17 Sep 2020 18:38:21

US3662101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:23:56

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 14:37:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:19:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:19:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:23:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:23:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:23:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:23:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '09:03'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '16 Sep 2020 09:03'	System	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '97.8' F	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Other (Other)'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'INFRARED THERMOMETER'	(b) (4)	
reason for change: Data Entry Error	Brenda Miller (b) (4)	24 Sep 2020 00:33:43
User entered 'TEMPORAL'	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:20:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '52'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'bpm'	System	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'breaths/min'	System	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '127'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '72'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:23:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:23:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '10:17'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '16 Sep 2020 10:17'	System	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '97.7' F	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Other (Other)'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'INFRARED THERMOMETER'	(b) (4)	
reason for change: Data Entry Error	Brenda Miller (b) (4)	24 Sep 2020 00:33:43
User entered 'TEMPORAL'	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:20:14
	(b) (4)	

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '62'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'bpm'	System	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'breaths/min'	System	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '136'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '83'	Brenda Miller (b) (4)	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	17 Sep 2020 14:20:14

US3662101

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:20:22

US3662101

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:20:22

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

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 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '09:45'	(b) (4) MaKayla Bishop (b) (4)	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '16 Sep 2020 09:45'	System	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'ONCE'	System	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 13:48:33

US3662101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:21:31

US3662101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:21:31

US3662101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '09:10'	Brenda Miller (b) (4)	17 Sep 2020 14:21:31

US3662101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '16 Sep 2020 09:10'	System	17 Sep 2020 14:21:31

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:23:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16 Sep 2020'	Brenda Miller (b) (4)	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '09:05'	Brenda Miller (b) (4)	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '16 Sep 2020 09:05'	System	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered empty.	System	17 Sep 2020 14:21:53

US3662101

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:22:08

US3662101

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	17 Sep 2020 14:22:08

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:18:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '02037557-ab67-4549-8cc3-7f36ccd96ab7' User entered 'Yes (Y)'	System	16 Sep 2020 14:19:08
	System	16 Sep 2020 14:19:08

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:18:51', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '02037557-ab67-4549-8cc3-7f36ccd96ab7' User entered '97.7'	System	16 Sep 2020 14:19:08
	System	16 Sep 2020 14:19:08

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:18:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '02037557-ab67-4549-8cc3-7f36ccd96ab7' User entered 'No (N)'	System	16 Sep 2020 14:19:08
	System	16 Sep 2020 14:19:08

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:19:04', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '02037557-ab67-4549-8cc3-7f36ccd96ab7' User entered '16 Sep 2020 10:19'	System	16 Sep 2020 14:19:08
	System	16 Sep 2020 14:19:08

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 10:05'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 12:35'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:57:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ce434e52-215c-4a71-9fa6-1f130aee87aa' User entered 'Yes (Y)'	System	16 Sep 2020 17:57:32
	System	16 Sep 2020 17:57:32

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:57:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ce434e52-215c-4a71-9fa6-1f130aee87aa' User entered '97.0'	System	16 Sep 2020 17:57:32
	System	16 Sep 2020 17:57:32

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:57:16', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ce434e52-215c-4a71-9fa6-1f130aee87aa' User entered 'No (N)'	System	16 Sep 2020 17:57:32
	System	16 Sep 2020 17:57:32

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:57:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ce434e52-215c-4a71-9fa6-1f130aee87aa' User entered '16 Sep 2020 13:57'	System	16 Sep 2020 17:57:32
	System	16 Sep 2020 17:57:32

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 13:30'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 2'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:22:39', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2bdd3b8f-3e05-416b-afab-d9febf31dea0' User entered 'Yes (Y)'	System	17 Sep 2020 23:23:15
	System	17 Sep 2020 23:23:15

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:22:56', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2bdd3b8f-3e05-416b-afab-d9febf31dea0' User entered '97.3'	System	17 Sep 2020 23:23:15
	System	17 Sep 2020 23:23:15

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:23:02', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2bdd3b8f-3e05-416b-afab-d9febf31dea0' User entered 'No (N)'	System	17 Sep 2020 23:23:15
	System	17 Sep 2020 23:23:15

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:23:09', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2bdd3b8f-3e05-416b-afab-d9febf31dea0' User entered '17 Sep 2020 19:23'	System	17 Sep 2020 23:23:15
	System	17 Sep 2020 23:23:15

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 3'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:43:14', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '12e79dc0-531f-4fee-b2e6-74f28fedac06' User entered 'Yes (Y)'	System	19 Sep 2020 00:43:50
	System	19 Sep 2020 00:43:50

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:43:33', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '12e79dc0-531f-4fee-b2e6-74f28fedac06' User entered '97.7'	System	19 Sep 2020 00:43:50
	System	19 Sep 2020 00:43:50

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:43:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '12e79dc0-531f-4fee-b2e6-74f28fedac06' User entered 'No (N)'	System	19 Sep 2020 00:43:50
	System	19 Sep 2020 00:43:50

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:43:47', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '12e79dc0-531f-4fee-b2e6-74f28fedac06' User entered '18 Sep 2020 20:43'	System	19 Sep 2020 00:43:50
	System	19 Sep 2020 00:43:50

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 4'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:04:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '319a3224-0145-4728-acc-e4f1e537092b' User entered 'Yes (Y)'	System	20 Sep 2020 00:05:24
	System	20 Sep 2020 00:05:24

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:08', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '319a3224-0145-4728-acc-e4f1e537092b' User entered '97.3'	System	20 Sep 2020 00:05:24
	System	20 Sep 2020 00:05:24

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:14', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '319a3224-0145-4728-acc-e4f1e537092b' User entered 'No (N)'	System	20 Sep 2020 00:05:24
	System	20 Sep 2020 00:05:24

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '319a3224-0145-4728-acc-e4f1e537092b' User entered '19 Sep 2020 20:05'	System	20 Sep 2020 00:05:24
	System	20 Sep 2020 00:05:24

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 5'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:50:56', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd39339cb-ec7f-4535-bee0-ed4ee06f9ddd' User entered 'Yes (Y)'	System	20 Sep 2020 22:51:31
	System	20 Sep 2020 22:51:31

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:51:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd39339cb-ec7f-4535-bee0-ed4ee06f9ddd' User entered '97.6'	System	20 Sep 2020 22:51:31
	System	20 Sep 2020 22:51:31

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:51:24', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd39339cb-ec7f-4535-bee0-ed4ee06f9ddd' User entered 'No (N)'	System	20 Sep 2020 22:51:31
	System	20 Sep 2020 22:51:31

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:51:28', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd39339cb-ec7f-4535-bee0-ed4ee06f9ddd' User entered '20 Sep 2020 18:51'	System	20 Sep 2020 22:51:31
	System	20 Sep 2020 22:51:31

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 6'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:37:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'aa7ee229-49a9-4a33-bb63-856ea614eded' User entered 'Yes (Y)'	System	21 Sep 2020 23:37:39
	System	21 Sep 2020 23:37:39

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:37:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'aa7ee229-49a9-4a33-bb63-856ea614eded' User entered '97.6'	System	21 Sep 2020 23:37:39
	System	21 Sep 2020 23:37:39

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:37:28', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'aa7ee229-49a9-4a33-bb63-856ea614eded' User entered 'No (N)'	System	21 Sep 2020 23:37:39
	System	21 Sep 2020 23:37:39

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:37:34', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'aa7ee229-49a9-4a33-bb63-856ea614eded' User entered '21 Sep 2020 19:37'	System	21 Sep 2020 23:37:39
	System	21 Sep 2020 23:37:39

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 7'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:25:41', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'b936f3f3-3fa3-47a8-82cb-92c865ca3b03'	System	22 Sep 2020 22:26:02
User entered 'Yes (Y)'	System	22 Sep 2020 22:26:02

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:25:47', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'b936f3f3-3fa3-47a8-82cb-92c865ca3b03'	System	22 Sep 2020 22:26:02
User entered '97.6'	System	22 Sep 2020 22:26:02

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:25:54', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'b936f3f3-3fa3-47a8-82cb-92c865ca3b03'	System	22 Sep 2020 22:26:02
User entered 'No (N)'	System	22 Sep 2020 22:26:02

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:25:59', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'b936f3f3-3fa3-47a8-82cb-92c865ca3b03'	System	22 Sep 2020 22:26:02
User entered '22 Sep 2020 18:25'	System	22 Sep 2020 22:26:02

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:19:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7d91dba0-2e3a-4ee7-982d-4f2c34e3c45c' User entered 'None (1)'	System	16 Sep 2020 14:19:57
	System	16 Sep 2020 14:19:57

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:19:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7d91dba0-2e3a-4ee7-982d-4f2c34e3c45c' User entered 'No (N)'	System	16 Sep 2020 14:19:57
	System	16 Sep 2020 14:19:57

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:19:38', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7d91dba0-2e3a-4ee7-982d-4f2c34e3c45c' User entered 'No (N)'	System	16 Sep 2020 14:19:57
	System	16 Sep 2020 14:19:57

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:19:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7d91dba0-2e3a-4ee7-982d-4f2c34e3c45c' User entered 'None (1)'	System	16 Sep 2020 14:19:57
	System	16 Sep 2020 14:19:57

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:19:55', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7d91dba0-2e3a-4ee7-982d-4f2c34e3c45c' User entered '16 Sep 2020 10:19'	System	16 Sep 2020 14:19:57
	System	16 Sep 2020 14:19:57

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 10:05'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 12:35'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:57:38', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e69c357e-54b5-4340-9815-b9cc8dfaa9b9' User entered 'None (1)'	System	16 Sep 2020 17:58:22
	System	16 Sep 2020 17:58:22

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:57:44', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e69c357e-54b5-4340-9815-b9cc8dfaa9b9' User entered 'No (N)'	System	16 Sep 2020 17:58:22
	System	16 Sep 2020 17:58:22

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:57:59', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e69c357e-54b5-4340-9815-b9cc8dfaa9b9' User entered 'No (N)'	System	16 Sep 2020 17:58:22
	System	16 Sep 2020 17:58:22

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:58:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e69c357e-54b5-4340-9815-b9cc8dfaa9b9' User entered 'None (1)'	System	16 Sep 2020 17:58:22
	System	16 Sep 2020 17:58:22

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:58:18', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e69c357e-54b5-4340-9815-b9cc8dfaa9b9' User entered '16 Sep 2020 13:58'	System	16 Sep 2020 17:58:22
	System	16 Sep 2020 17:58:22

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 13:30'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 2'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:23:23', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '68e355e0-4422-4b26-a340-79455873f2fd'	System	17 Sep 2020 23:24:17
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 23:24:17

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:23:29', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '68e355e0-4422-4b26-a340-79455873f2fd' User entered 'No (N)'	System	17 Sep 2020 23:24:17
	System	17 Sep 2020 23:24:17

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:23:34', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '68e355e0-4422-4b26-a340-79455873f2fd' User entered 'Yes (Y)'	System	17 Sep 2020 23:24:17
	System	17 Sep 2020 23:24:17

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:23:49', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '68e355e0-4422-4b26-a340-79455873f2fd' User entered '3'	System	17 Sep 2020 23:24:17
	System	17 Sep 2020 23:24:17

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:23:59', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '68e355e0-4422-4b26-a340-79455873f2fd' User entered 'None (1)'	System	17 Sep 2020 23:24:17
	System	17 Sep 2020 23:24:17

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:16', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '68e355e0-4422-4b26-a340-79455873f2fd' User entered '17 Sep 2020 19:24'	System	17 Sep 2020 23:24:17
	System	17 Sep 2020 23:24:17

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 3'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:43:59', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '27a39d08-20fe-4a54-8f7e-4d5f6a544249'	System	19 Sep 2020 00:44:18
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 00:44:18

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:03', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '27a39d08-20fe-4a54-8f7e-4d5f6a544249' User entered 'No (N)'	System	19 Sep 2020 00:44:18
	System	19 Sep 2020 00:44:18

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:08', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '27a39d08-20fe-4a54-8f7e-4d5f6a544249' User entered 'No (N)'	System	19 Sep 2020 00:44:18
	System	19 Sep 2020 00:44:18

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:12', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '27a39d08-20fe-4a54-8f7e-4d5f6a544249'	System	19 Sep 2020 00:44:18
User entered 'None (1)'	System	19 Sep 2020 00:44:18

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:16', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '27a39d08-20fe-4a54-8f7e-4d5f6a544249' User entered '18 Sep 2020 20:44'	System	19 Sep 2020 00:44:18
	System	19 Sep 2020 00:44:18

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 4'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2213b4c5-1c59-4ae9-adff-8fb417d539e8'	System	20 Sep 2020 00:05:49
User entered 'None (1)'	System	20 Sep 2020 00:05:49

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2213b4c5-1c59-4ae9-adff-8fb417d539e8' User entered 'No (N)'	System	20 Sep 2020 00:05:49
	System	20 Sep 2020 00:05:49

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:36', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2213b4c5-1c59-4ae9-adff-8fb417d539e8' User entered 'No (N)'	System	20 Sep 2020 00:05:49
	System	20 Sep 2020 00:05:49

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2213b4c5-1c59-4ae9-adff-8fb417d539e8'	System	20 Sep 2020 00:05:49
User entered 'None (1)'	System	20 Sep 2020 00:05:49

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2213b4c5-1c59-4ae9-adff-8fb417d539e8' User entered '19 Sep 2020 20:05'	System	20 Sep 2020 00:05:49
	System	20 Sep 2020 00:05:49

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 5'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:51:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'db0b8f89-bc85-484f-8d0a-01d119ca9448'	System	20 Sep 2020 22:52:13
User entered 'None (1)'	System	20 Sep 2020 22:52:13

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:51:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'db0b8f89-bc85-484f-8d0a-01d119ca9448'	System	20 Sep 2020 22:52:13
User entered 'No (N)'	System	20 Sep 2020 22:52:13

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:01', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'db0b8f89-bc85-484f-8d0a-01d119ca9448'	System	20 Sep 2020 22:52:13
User entered 'No (N)'	System	20 Sep 2020 22:52:13

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'db0b8f89-bc85-484f-8d0a-01d119ca9448'	System	20 Sep 2020 22:52:13
User entered 'None (1)'	System	20 Sep 2020 22:52:13

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'db0b8f89-bc85-484f-8d0a-01d119ca9448'	System	20 Sep 2020 22:52:13
User entered '20 Sep 2020 18:52'	System	20 Sep 2020 22:52:13

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 6'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:38:04', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a9eea1d9-7415-427b-acb0-3d656654015b' User entered 'None (1)'	System	21 Sep 2020 23:39:00
	System	21 Sep 2020 23:39:00

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:38:14', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a9eea1d9-7415-427b-acb0-3d656654015b' User entered 'No (N)'	System	21 Sep 2020 23:39:00
	System	21 Sep 2020 23:39:00

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:38:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a9eea1d9-7415-427b-acb0-3d656654015b' User entered 'No (N)'	System	21 Sep 2020 23:39:00
	System	21 Sep 2020 23:39:00

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:38:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a9eea1d9-7415-427b-acb0-3d656654015b' User entered 'None (1)'	System	21 Sep 2020 23:39:00
	System	21 Sep 2020 23:39:00

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:38:55', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a9eea1d9-7415-427b-acb0-3d656654015b' User entered '21 Sep 2020 19:38'	System	21 Sep 2020 23:39:00
	System	21 Sep 2020 23:39:00

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 7'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:26:24', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0033cd2e-4019-4d2c-8128-e4de1c06e496'	System	22 Sep 2020 22:26:41
User entered 'None (1)'	System	22 Sep 2020 22:26:41

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:26:28', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0033cd2e-4019-4d2c-8128-e4de1c06e496' User entered 'No (N)'	System	22 Sep 2020 22:26:41
	System	22 Sep 2020 22:26:41

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:26:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0033cd2e-4019-4d2c-8128-e4de1c06e496' User entered 'No (N)'	System	22 Sep 2020 22:26:41
	System	22 Sep 2020 22:26:41

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:26:37', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0033cd2e-4019-4d2c-8128-e4de1c06e496'	System	22 Sep 2020 22:26:41
User entered 'None (1)'	System	22 Sep 2020 22:26:41

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:26:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0033cd2e-4019-4d2c-8128-e4de1c06e496' User entered '22 Sep 2020 18:26'	System	22 Sep 2020 22:26:41
	System	22 Sep 2020 22:26:41

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:01', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered 'None (0)'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:05', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered 'None (0)'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:09', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered 'None (0)'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:13', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered 'None (0)'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:19', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered 'None (0)'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:22', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered 'None (0)'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered 'No (N)'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T10:20:33', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '6d36adcd-d93c-4a85-ac0e-a8d9810986f2' User entered '16 Sep 2020 10:20'	System	16 Sep 2020 14:20:39
	System	16 Sep 2020 14:20:39

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 10:05'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 12:35'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:58:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c'	System	16 Sep 2020 17:59:37
User entered 'No interference with activity (1)'	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:59:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c' User entered 'No interference with activity (1)'	System	16 Sep 2020 17:59:37
	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:59:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c' User entered 'None (0)'	System	16 Sep 2020 17:59:37
	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:59:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c' User entered 'None (0)'	System	16 Sep 2020 17:59:37
	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:59:21', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c' User entered 'None (0)'	System	16 Sep 2020 17:59:37
	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:59:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c' User entered 'None (0)'	System	16 Sep 2020 17:59:37
	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:59:30', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c' User entered 'No (N)'	System	16 Sep 2020 17:59:37
	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-16T13:59:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e62c747b-ffc7-43b7-bef3-2877587caa6c' User entered '16 Sep 2020 13:59'	System	16 Sep 2020 17:59:37
	System	16 Sep 2020 17:59:37

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Sep 2020 13:30'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 2'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered 'None (0)'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:34', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered 'No interference with activity (1)'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered 'None (0)'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:44', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered 'None (0)'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:47', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered 'None (0)'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:51', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered 'None (0)'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:24:56', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered 'No (N)'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-17T19:25:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '96be6c22-a767-497a-8881-2410fd47408b' User entered '17 Sep 2020 19:25'	System	17 Sep 2020 23:25:01
	System	17 Sep 2020 23:25:01

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 3'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:28', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12' User entered 'None (0)'	System	19 Sep 2020 00:45:06
	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:34', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12'	System	19 Sep 2020 00:45:06
User entered 'No interference with activity (1)'	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12' User entered 'None (0)'	System	19 Sep 2020 00:45:06
	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12' User entered 'None (0)'	System	19 Sep 2020 00:45:06
	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:49', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12' User entered 'None (0)'	System	19 Sep 2020 00:45:06
	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:51', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12' User entered 'None (0)'	System	19 Sep 2020 00:45:06
	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:44:57', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12'	System	19 Sep 2020 00:45:06
User entered 'No (N)'	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-18T20:45:01', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '9f0c1a3a-14e3-4e9e-8eaa-cbe4ab1efc12' User entered '18 Sep 2020 20:45'	System	19 Sep 2020 00:45:06
	System	19 Sep 2020 00:45:06

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 4'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:54', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered 'None (0)'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:05:59', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered 'None (0)'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:06:03', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered 'None (0)'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:06:14', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered 'None (0)'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:06:17', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered 'None (0)'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:06:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered 'None (0)'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:06:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered 'No (N)'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-19T20:06:30', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd25afd3a-6abf-4a44-8858-0e74662d424b' User entered '19 Sep 2020 20:06'	System	20 Sep 2020 00:06:32
	System	20 Sep 2020 00:06:32

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 5'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:24', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528'	System	20 Sep 2020 22:52:52
User entered 'No interference with activity (1)'	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528' User entered 'None (0)'	System	20 Sep 2020 22:52:52
	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528' User entered 'None (0)'	System	20 Sep 2020 22:52:52
	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528' User entered 'None (0)'	System	20 Sep 2020 22:52:52
	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:38', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528' User entered 'None (0)'	System	20 Sep 2020 22:52:52
	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:41', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528' User entered 'None (0)'	System	20 Sep 2020 22:52:52
	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528' User entered 'No (N)'	System	20 Sep 2020 22:52:52
	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-20T18:52:50', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '08096fdd-c055-431e-b5d5-617dfa947528' User entered '20 Sep 2020 18:52'	System	20 Sep 2020 22:52:52
	System	20 Sep 2020 22:52:52

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 6'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:01', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered 'None (0)'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:07', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered 'None (0)'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:13', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered 'None (0)'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered 'None (0)'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered 'None (0)'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:38', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered 'None (0)'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:45', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered 'No (N)'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-21T19:39:49', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a1ccc425-e239-443d-b21c-71112dd6515b' User entered '21 Sep 2020 19:39'	System	21 Sep 2020 23:39:51
	System	21 Sep 2020 23:39:51

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 7'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:05', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered 'None (0)'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:14', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered 'None (0)'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:19', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered 'None (0)'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:22', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered 'None (0)'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered 'None (0)'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:29', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered 'None (0)'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:39', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered 'No (N)'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-09-22T18:27:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ec2e348-198a-490d-b2a0-1399323e6a38' User entered '22 Sep 2020 18:27'	System	22 Sep 2020 22:27:44
	System	22 Sep 2020 22:27:44

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:48:33

US3662101

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 14:38:53

US3662101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '23 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 14:38:53

US3662101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	23 Sep 2020 14:38:53

US3662101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 14:38:53

US3662101

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	01 Oct 2020 19:22:54

US3662101

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	01 Oct 2020 19:22:54

US3662101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	01 Oct 2020 19:23:09

US3662101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Oct 2020'	Brenda Miller (b) (4)	01 Oct 2020 19:23:09

US3662101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	01 Oct 2020 19:23:09

US3662101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	01 Oct 2020 19:23:09

US3662101

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Oct 2020 19:56:37

US3662101

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	08 Oct 2020 19:56:37

US3662101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Oct 2020 19:56:52

US3662101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '08 Oct 2020'	Brenda Miller (b) (4)	08 Oct 2020 19:56:52

US3662101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	08 Oct 2020 19:56:52

US3662101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	08 Oct 2020 19:56:52

US3662101

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Oct 2020 19:58:22

US3662101

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	08 Oct 2020 19:58:22

US3662101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	15 Oct 2020 15:23:57

US3662101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	(b) (4) Brenda Miller (b) (4)	15 Oct 2020 15:23:57

US3662101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[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 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	15 Oct 2020 15:23:57

US3662101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'VISIT2'	System	15 Oct 2020 15:23:57

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '07:56'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '14 Oct 2020 07:56'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '97.9' F	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Other (Other)'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '60'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'bpm'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'breaths/min'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '170'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '68'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '09:19'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '14 Oct 2020 09:19'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '98.2' F	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Other (Other)'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '59'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'bpm'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'breaths/min'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '150'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '66'	Brenda Miller (b) (4)	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	15 Oct 2020 15:26:13

US3662101

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:26:35

US3662101

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:26:35

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

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 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '08:46'	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '14 Oct 2020 08:46'	System	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'ONCE'	System	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:23:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 12:49:49

US3662101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:27:07

US3662101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:27:07

US3662101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '08:15'	Brenda Miller (b) (4)	15 Oct 2020 15:27:07

US3662101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '14 Oct 2020 08:15'	System	15 Oct 2020 15:27:07

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:23:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '08:10'	Brenda Miller (b) (4)	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '14 Oct 2020 08:10'	System	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered empty.	System	15 Oct 2020 15:27:26

US3662101

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:27:33

US3662101

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	15 Oct 2020 15:27:33

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:14', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '72d013c2-9e64-4187-a460-7e9f8651ff5f' User entered 'Yes (Y)'	System	14 Oct 2020 13:21:35
	System	14 Oct 2020 13:21:35

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:22', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '72d013c2-9e64-4187-a460-7e9f8651ff5f' User entered '98.2'	System	14 Oct 2020 13:21:35
	System	14 Oct 2020 13:21:35

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:26', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '72d013c2-9e64-4187-a460-7e9f8651ff5f' User entered 'No (N)'	System	14 Oct 2020 13:21:35
	System	14 Oct 2020 13:21:35

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '72d013c2-9e64-4187-a460-7e9f8651ff5f' User entered '14 Oct 2020 09:21'	System	14 Oct 2020 13:21:35
	System	14 Oct 2020 13:21:35

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 09:06'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 11:36'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:34:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd27bd597-9333-449c-97e3-744d8e1abb5c' User entered 'Yes (Y)'	System	14 Oct 2020 21:35:07
	System	14 Oct 2020 21:35:07

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:34:30', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd27bd597-9333-449c-97e3-744d8e1abb5c' User entered '97.3'	System	14 Oct 2020 21:35:07
	System	14 Oct 2020 21:35:07

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:34:37', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd27bd597-9333-449c-97e3-744d8e1abb5c'	System	14 Oct 2020 21:35:07
User entered 'Yes (Y)'	System	14 Oct 2020 21:35:07

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will key with safety call' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 07:41:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	michelle saemann (b) (4)	21 Oct 2020 12:02:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:34:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd27bd597-9333-449c-97e3-744d8e1abb5c'	System	14 Oct 2020 21:35:07
User entered '1'	System	14 Oct 2020 21:35:07

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:34:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd27bd597-9333-449c-97e3-744d8e1abb5c' User entered '0'	System	14 Oct 2020 21:35:07
	System	14 Oct 2020 21:35:07

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:35:01', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd27bd597-9333-449c-97e3-744d8e1abb5c' User entered '14 Oct 2020 17:35'	System	14 Oct 2020 21:35:07
	System	14 Oct 2020 21:35:07

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 12:31'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 2'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:45:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '44615777-dd84-4541-b420-65460a8d1332'	System	15 Oct 2020 21:45:45
User entered 'Yes (Y)'	System	15 Oct 2020 21:45:45

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:45:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '44615777-dd84-4541-b420-65460a8d1332' User entered '99.3'	System	15 Oct 2020 21:45:45
	System	15 Oct 2020 21:45:45

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:45:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '44615777-dd84-4541-b420-65460a8d1332'	System	15 Oct 2020 21:45:45
User entered 'Yes (Y)'	System	15 Oct 2020 21:45:45

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will key with safety call' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 07:42:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	michelle saemann (b) (4)	21 Oct 2020 12:03:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:45:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '44615777-dd84-4541-b420-65460a8d1332'	System	15 Oct 2020 21:45:45
User entered '1'	System	15 Oct 2020 21:45:45

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:45:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '44615777-dd84-4541-b420-65460a8d1332' User entered '0'	System	15 Oct 2020 21:45:45
	System	15 Oct 2020 21:45:45

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:45:41', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '44615777-dd84-4541-b420-65460a8d1332'	System	15 Oct 2020 21:45:45
User entered '15 Oct 2020 17:45'	System	15 Oct 2020 21:45:45

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 3'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:41:18', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2ccb96d5-d496-4940-9347-cefb68b34e15' User entered 'Yes (Y)'	System	16 Oct 2020 22:41:46
	System	16 Oct 2020 22:41:46

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:41:26', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2ccb96d5-d496-4940-9347-cefb68b34e15' User entered '97.7'	System	16 Oct 2020 22:41:46
	System	16 Oct 2020 22:41:46

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:41:30', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2ccb96d5-d496-4940-9347-cefb68b34e15' User entered 'No (N)'	System	16 Oct 2020 22:41:46
	System	16 Oct 2020 22:41:46

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:41:41', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2ccb96d5-d496-4940-9347-cefb68b34e15' User entered '16 Oct 2020 18:41'	System	16 Oct 2020 22:41:46
	System	16 Oct 2020 22:41:46

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 4'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:49:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1a2606a7-8052-4c51-8aa8-0e43d2034826' User entered 'Yes (Y)'	System	17 Oct 2020 23:50:13
	System	17 Oct 2020 23:50:13

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:49:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1a2606a7-8052-4c51-8aa8-0e43d2034826' User entered '98.0'	System	17 Oct 2020 23:50:13
	System	17 Oct 2020 23:50:13

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:49:34', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1a2606a7-8052-4c51-8aa8-0e43d2034826' User entered 'Yes (Y)'	System	17 Oct 2020 23:50:13
	System	17 Oct 2020 23:50:13

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will key with safety call' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 07:42:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	michelle saemann (b) (4)	21 Oct 2020 12:03:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:49:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1a2606a7-8052-4c51-8aa8-0e43d2034826'	System	17 Oct 2020 23:50:13
User entered '1'	System	17 Oct 2020 23:50:13

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:49:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1a2606a7-8052-4c51-8aa8-0e43d2034826' User entered '0'	System	17 Oct 2020 23:50:13
	System	17 Oct 2020 23:50:13

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:50:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1a2606a7-8052-4c51-8aa8-0e43d2034826' User entered '17 Oct 2020 19:50'	System	17 Oct 2020 23:50:13
	System	17 Oct 2020 23:50:13

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 5'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:07:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8676d5f2-fee0-49e4-a1ff-36959e9970b5' User entered 'Yes (Y)'	System	18 Oct 2020 21:08:11
	System	18 Oct 2020 21:08:11

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:07:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8676d5f2-fee0-49e4-a1ff-36959e9970b5' User entered '97.7'	System	18 Oct 2020 21:08:11
	System	18 Oct 2020 21:08:11

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:07:34', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8676d5f2-fee0-49e4-a1ff-36959e9970b5' User entered 'No (N)'	System	18 Oct 2020 21:08:11
	System	18 Oct 2020 21:08:11

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:08:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8676d5f2-fee0-49e4-a1ff-36959e9970b5' User entered '18 Oct 2020 17:08'	System	18 Oct 2020 21:08:11
	System	18 Oct 2020 21:08:11

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 6'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:01:29', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '735b031f-5b1d-47eb-a957-751ad92cd891' User entered 'Yes (Y)'	System	19 Oct 2020 21:01:55
	System	19 Oct 2020 21:01:55

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:01:38', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '735b031f-5b1d-47eb-a957-751ad92cd891' User entered '97.7'	System	19 Oct 2020 21:01:55
	System	19 Oct 2020 21:01:55

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:01:42', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '735b031f-5b1d-47eb-a957-751ad92cd891'	System	19 Oct 2020 21:01:55
User entered 'No (N)'	System	19 Oct 2020 21:01:55

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:01:53', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '735b031f-5b1d-47eb-a957-751ad92cd891' User entered '19 Oct 2020 17:01'	System	19 Oct 2020 21:01:55
	System	19 Oct 2020 21:01:55

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 7'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:17:15', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '48e5528b-fa45-447f-9e4c-bf5f4e8c9fb7' User entered 'Yes (Y)'	System	20 Oct 2020 23:17:42
	System	20 Oct 2020 23:17:42

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:17:26', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '48e5528b-fa45-447f-9e4c-bf5f4e8c9fb7' User entered '98.0'	System	20 Oct 2020 23:17:42
	System	20 Oct 2020 23:17:42

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:17:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '48e5528b-fa45-447f-9e4c-bf5f4e8c9fb7'	System	20 Oct 2020 23:17:42
User entered 'No (N)'	System	20 Oct 2020 23:17:42

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:17:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '48e5528b-fa45-447f-9e4c-bf5f4e8c9fb7' User entered '20 Oct 2020 19:17'	System	20 Oct 2020 23:17:42
	System	20 Oct 2020 23:17:42

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0ad02f67-f812-4319-8bcb-4f7d23f02519'	System	14 Oct 2020 13:21:58
User entered 'None (1)'	System	14 Oct 2020 13:21:58

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:44', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0ad02f67-f812-4319-8bcb-4f7d23f02519' User entered 'No (N)'	System	14 Oct 2020 13:21:58
	System	14 Oct 2020 13:21:58

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:47', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0ad02f67-f812-4319-8bcb-4f7d23f02519' User entered 'No (N)'	System	14 Oct 2020 13:21:58
	System	14 Oct 2020 13:21:58

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:52', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0ad02f67-f812-4319-8bcb-4f7d23f02519'	System	14 Oct 2020 13:21:58
User entered 'None (1)'	System	14 Oct 2020 13:21:58

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:21:55', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0ad02f67-f812-4319-8bcb-4f7d23f02519' User entered '14 Oct 2020 09:21'	System	14 Oct 2020 13:21:58
	System	14 Oct 2020 13:21:58

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 09:06'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 11:36'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:35:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2fc90158-23fd-47c9-8cb5-3fc8a6541673'	System	14 Oct 2020 21:36:05
User entered 'None (1)'	System	14 Oct 2020 21:36:05

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:35:24', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2fc90158-23fd-47c9-8cb5-3fc8a6541673' User entered 'No (N)'	System	14 Oct 2020 21:36:05
	System	14 Oct 2020 21:36:05

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:35:28', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2fc90158-23fd-47c9-8cb5-3fc8a6541673' User entered 'No (N)'	System	14 Oct 2020 21:36:05
	System	14 Oct 2020 21:36:05

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:35:52', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2fc90158-23fd-47c9-8cb5-3fc8a6541673'	System	14 Oct 2020 21:36:05
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 21:36:05

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:35:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2fc90158-23fd-47c9-8cb5-3fc8a6541673' User entered '14 Oct 2020 17:35'	System	14 Oct 2020 21:36:05
	System	14 Oct 2020 21:36:05

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 12:31'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 2'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:46:02', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1f2c7cd7-af0e-45be-9e55-b385afff005c'	System	15 Oct 2020 21:46:22
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 21:46:22

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:46:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1f2c7cd7-af0e-45be-9e55-b385afff005c' User entered 'No (N)'	System	15 Oct 2020 21:46:22
	System	15 Oct 2020 21:46:22

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:46:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1f2c7cd7-af0e-45be-9e55-b385afff005c' User entered 'No (N)'	System	15 Oct 2020 21:46:22
	System	15 Oct 2020 21:46:22

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:46:15', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1f2c7cd7-af0e-45be-9e55-b385afff005c'	System	15 Oct 2020 21:46:22
User entered 'None (1)'	System	15 Oct 2020 21:46:22

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:46:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1f2c7cd7-af0e-45be-9e55-b385afff005c' User entered '15 Oct 2020 17:46'	System	15 Oct 2020 21:46:22
	System	15 Oct 2020 21:46:22

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 3'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:42:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f308f845-fd7e-46fd-b3c7-7ac37f9c7610'	System	16 Oct 2020 22:42:39
User entered 'None (1)'	System	16 Oct 2020 22:42:39

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:42:17', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f308f845-fd7e-46fd-b3c7-7ac37f9c7610' User entered 'No (N)'	System	16 Oct 2020 22:42:39
	System	16 Oct 2020 22:42:39

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:42:20', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f308f845-fd7e-46fd-b3c7-7ac37f9c7610' User entered 'No (N)'	System	16 Oct 2020 22:42:39
	System	16 Oct 2020 22:42:39

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:42:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f308f845-fd7e-46fd-b3c7-7ac37f9c7610'	System	16 Oct 2020 22:42:39
User entered 'None (1)'	System	16 Oct 2020 22:42:39

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:42:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f308f845-fd7e-46fd-b3c7-7ac37f9c7610' User entered '16 Oct 2020 18:42'	System	16 Oct 2020 22:42:39
	System	16 Oct 2020 22:42:39

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 4'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:50:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '93186ed4-d94d-4289-b87c-57bee2e42acc'	System	17 Oct 2020 23:50:54
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 23:50:54

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:50:38', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '93186ed4-d94d-4289-b87c-57bee2e42acc' User entered 'No (N)'	System	17 Oct 2020 23:50:54
	System	17 Oct 2020 23:50:54

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:50:42', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '93186ed4-d94d-4289-b87c-57bee2e42acc' User entered 'No (N)'	System	17 Oct 2020 23:50:54
	System	17 Oct 2020 23:50:54

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:50:47', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '93186ed4-d94d-4289-b87c-57bee2e42acc' User entered 'None (1)'	System	17 Oct 2020 23:50:54
	System	17 Oct 2020 23:50:54

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:50:53', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '93186ed4-d94d-4289-b87c-57bee2e42acc' User entered '17 Oct 2020 19:50'	System	17 Oct 2020 23:50:54
	System	17 Oct 2020 23:50:54

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 5'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:08:22', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3b1454b6-fa5c-4f22-b251-11a04caf47cd'	System	18 Oct 2020 21:08:44
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 21:08:44

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:08:28', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3b1454b6-fa5c-4f22-b251-11a04caf47cd' User entered 'No (N)'	System	18 Oct 2020 21:08:44
	System	18 Oct 2020 21:08:44

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:08:31', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3b1454b6-fa5c-4f22-b251-11a04caf47cd' User entered 'No (N)'	System	18 Oct 2020 21:08:44
	System	18 Oct 2020 21:08:44

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:08:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3b1454b6-fa5c-4f22-b251-11a04caf47cd' User entered 'None (1)'	System	18 Oct 2020 21:08:44
	System	18 Oct 2020 21:08:44

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:08:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3b1454b6-fa5c-4f22-b251-11a04caf47cd' User entered '18 Oct 2020 17:08'	System	18 Oct 2020 21:08:44
	System	18 Oct 2020 21:08:44

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 6'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '24e3e1f3-f032-4170-b781-1b4f7800f7df' User entered 'None (1)'	System	19 Oct 2020 21:02:17
	System	19 Oct 2020 21:02:17

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:04', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '24e3e1f3-f032-4170-b781-1b4f7800f7df' User entered 'No (N)'	System	19 Oct 2020 21:02:17
	System	19 Oct 2020 21:02:17

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:07', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '24e3e1f3-f032-4170-b781-1b4f7800f7df' User entered 'No (N)'	System	19 Oct 2020 21:02:17
	System	19 Oct 2020 21:02:17

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:12', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '24e3e1f3-f032-4170-b781-1b4f7800f7df' User entered 'None (1)'	System	19 Oct 2020 21:02:17
	System	19 Oct 2020 21:02:17

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:15', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '24e3e1f3-f032-4170-b781-1b4f7800f7df' User entered '19 Oct 2020 17:02'	System	19 Oct 2020 21:02:17
	System	19 Oct 2020 21:02:17

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 7'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:17:49', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ebe6f4e-12b2-49d5-bda9-f7eeb05c16d9'	System	20 Oct 2020 23:18:19
User entered 'None (1)'	System	20 Oct 2020 23:18:19

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:17:52', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ebe6f4e-12b2-49d5-bda9-f7eeb05c16d9' User entered 'No (N)'	System	20 Oct 2020 23:18:19
	System	20 Oct 2020 23:18:19

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:17:57', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ebe6f4e-12b2-49d5-bda9-f7eeb05c16d9' User entered 'No (N)'	System	20 Oct 2020 23:18:19
	System	20 Oct 2020 23:18:19

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ebe6f4e-12b2-49d5-bda9-f7eeb05c16d9' User entered 'None (1)'	System	20 Oct 2020 23:18:19
	System	20 Oct 2020 23:18:19

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:17', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ebe6f4e-12b2-49d5-bda9-f7eeb05c16d9' User entered '20 Oct 2020 19:18'	System	20 Oct 2020 23:18:19
	System	20 Oct 2020 23:18:19

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered 'None (0)'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:03', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered 'None (0)'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered 'None (0)'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:12', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered 'None (0)'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:15', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered 'None (0)'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:18', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered 'None (0)'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered 'No (N)'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T09:22:29', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'ae072057-b27e-4db8-9752-b7c4f0275b3b' User entered '14 Oct 2020 09:22'	System	14 Oct 2020 13:22:33
	System	14 Oct 2020 13:22:33

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 09:06'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 11:36'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:36:42', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:36:53', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered 'Some interference with activity (2)'	System	14 Oct 2020 21:38:37
	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:38:22', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered 'No interference with activity (1)'	System	14 Oct 2020 21:38:37
	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:37:11', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered 'No interference with activity (1)'	System	14 Oct 2020 21:38:37
	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:37:15', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered 'None (0)'	System	14 Oct 2020 21:38:37
	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:37:19', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered 'No interference with activity (1)'	System	14 Oct 2020 21:38:37
	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:37:24', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered 'No (N)'	System	14 Oct 2020 21:38:37
	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-14T17:38:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a274f565-338a-4ef9-93a3-9c53b7433edb' User entered '14 Oct 2020 17:38'	System	14 Oct 2020 21:38:37
	System	14 Oct 2020 21:38:37

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '14 Oct 2020 12:31'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 2'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:46:52', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8'	System	15 Oct 2020 21:48:00
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:47:04', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8'	System	15 Oct 2020 21:48:00
User entered 'Significant; prevents daily activity (3)'	System	15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:47:17', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8'	System	15 Oct 2020 21:48:00
User entered 'Some interference with activity (2)'	System	15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:47:23', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8' User entered 'None (0)'	System	15 Oct 2020 21:48:00
	System	15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:47:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8' User entered 'None (0)'	System	15 Oct 2020 21:48:00
	System	15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:47:34', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8' User entered 'None (0)'	System	15 Oct 2020 21:48:00
	System	15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:47:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8' User entered 'No (N)'	System	15 Oct 2020 21:48:00
	System	15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-15T17:47:57', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e2b90775-2af9-4aae-87f9-2a04db55b0b8' User entered '15 Oct 2020 17:47'	System	15 Oct 2020 21:48:00
	System	15 Oct 2020 21:48:00

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 3'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:21', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered 'None (0)'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered 'None (0)'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered 'None (0)'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:37', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered 'None (0)'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered 'None (0)'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered 'None (0)'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered 'No (N)'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-16T18:43:52', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '78b70f8e-44a0-47d6-b8e2-bbcc282d3fab' User entered '16 Oct 2020 18:43'	System	16 Oct 2020 22:43:57
	System	16 Oct 2020 22:43:57

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 4'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:51:09', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2'	System	17 Oct 2020 23:52:25
User entered 'No interference with activity (1)'	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:51:18', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2'	System	17 Oct 2020 23:52:25
User entered 'Some interference with activity (2)'	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:51:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2'	System	17 Oct 2020 23:52:25
User entered 'Some interference with activity (2)'	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:52:01', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2'	System	17 Oct 2020 23:52:25
User entered 'No interference with activity (1)'	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:52:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2'	System	17 Oct 2020 23:52:25
User entered 'None (0)'	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:52:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2'	System	17 Oct 2020 23:52:25
User entered 'None (0)'	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:52:16', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2'	System	17 Oct 2020 23:52:25
User entered 'No (N)'	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-17T19:52:21', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '8ef67a7a-9065-423b-95fa-56cf255dbab2' User entered '17 Oct 2020 19:52'	System	17 Oct 2020 23:52:25
	System	17 Oct 2020 23:52:25

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 5'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:08:47', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2'	System	18 Oct 2020 21:10:24
User entered 'No interference with activity (1)'	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:09:01', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2'	System	18 Oct 2020 21:10:24
User entered 'Some interference with activity (2)'	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:09:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2' User entered 'None (0)'	System	18 Oct 2020 21:10:24
	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:09:16', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2' User entered 'None (0)'	System	18 Oct 2020 21:10:24
	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:09:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2' User entered 'None (0)'	System	18 Oct 2020 21:10:24
	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:09:45', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2'	System	18 Oct 2020 21:10:24
User entered 'No interference with activity (1)'	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:09:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2' User entered 'No (N)'	System	18 Oct 2020 21:10:24
	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-18T17:10:22', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'cef886ed-d189-4b0b-9346-52e723ad16e2' User entered '18 Oct 2020 17:10'	System	18 Oct 2020 21:10:24
	System	18 Oct 2020 21:10:24

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 6'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:21', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered 'None (0)'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:24', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered 'None (0)'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:27', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered 'None (0)'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:30', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered 'None (0)'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered 'None (0)'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered 'None (0)'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:41', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered 'No (N)'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-19T17:02:44', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'df487c06-c56e-418e-9a00-78bf0674397f' User entered '19 Oct 2020 17:02'	System	19 Oct 2020 21:02:45
	System	19 Oct 2020 21:02:45

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	14 Oct 2020 12:49:49
User entered 'Day 7'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5' User entered 'None (0)'	System	20 Oct 2020 23:19:10
	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:45', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5' User entered 'None (0)'	System	20 Oct 2020 23:19:10
	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:49', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5' User entered 'None (0)'	System	20 Oct 2020 23:19:10
	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:52', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5' User entered 'None (0)'	System	20 Oct 2020 23:19:10
	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:55', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5' User entered 'None (0)'	System	20 Oct 2020 23:19:10
	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:18:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5' User entered 'None (0)'	System	20 Oct 2020 23:19:10
	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:19:02', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5'	System	20 Oct 2020 23:19:10
User entered 'No (N)'	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-10-20T19:19:07', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'bb4f5cf3-3b65-4e28-86a2-4b693f192ad5' User entered '20 Oct 2020 19:19'	System	20 Oct 2020 23:19:10
	System	20 Oct 2020 23:19:10

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 12:49:49

US3662101

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:23:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 12:49:49

US3662101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	22 Oct 2020 17:44:13

US3662101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '21 Oct 2020'	Brenda Miller (b) (4)	22 Oct 2020 17:44:13

US3662101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	22 Oct 2020 17:44:13

US3662101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	22 Oct 2020 17:44:13

US3662101

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	22 Oct 2020 17:44:19

US3662101

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	22 Oct 2020 17:44:19

US3662101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:38:29

US3662101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '28 Oct 2020'	Brenda Miller (b) (4)	31 Oct 2020 19:38:29

US3662101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	31 Oct 2020 19:38:29

US3662101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	31 Oct 2020 19:38:29

US3662101

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:38:34

US3662101

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	31 Oct 2020 19:38:34

US3662101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:03:12

US3662101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '04 Nov 2020'	Brenda Miller (b) (4)	08 Nov 2020 17:03:12

US3662101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	08 Nov 2020 17:03:12

US3662101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 17:03:12

US3662101

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:03:19

US3662101

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	08 Nov 2020 17:03:19

US3662101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:45:17

US3662101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Nov 2020'	(b) (4) Brenda Miller (b) (4)	16 Nov 2020 17:45:17

US3662101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[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 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	16 Nov 2020 17:45:17

US3662101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'VISIT3'	System	16 Nov 2020 17:45:17

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Nov 2020'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '08:10'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '12 Nov 2020 08:10'	System	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '97.7' F	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Other (Other)'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '51'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'bpm'	System	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '16'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'breaths/min'	System	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '134'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '80'	Brenda Miller (b) (4)	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered 'mmHg'	System	16 Nov 2020 17:45:57

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29

US3662101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:23:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29

US3662101

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:46:09

US3662101

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:23:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Nov 2020'	Brenda Miller (b) (4)	16 Nov 2020 17:46:09

US3662101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:46:32

US3662101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 12Nov2020. However, test result date is missing in GCL. Please confirm if 12NOV2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 06:41:08
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 12Nov2020. However, test result date is missing in GCL. Please confirm if 12NOV2020 is correct date to update in GCL records.' answered with 'correct date is 12nov2020 ' (Site from DM).	michelle saemann (b) (4) (b) (4)	26 Nov 2020 03:15:25
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 12Nov2020. However, test result date is missing in GCL. Please confirm if 12NOV2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:28:24
User entered '12 Nov 2020'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 17:46:32

US3662101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '08:30'	Brenda Miller (b) (4)	16 Nov 2020 17:46:32

US3662101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '12 Nov 2020 08:30'	System	16 Nov 2020 17:46:32

US3662101

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:46:44

US3662101

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	16 Nov 2020 17:46:44

US3662101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered 'Day 64'	System	16 Sep 2020 13:48:33

US3662101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-17T13:02:47', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a037d762-49d7-4d59-be48-5605fb556160'	System	17 Nov 2020 18:03:08
User entered 'No (N)'	System	17 Nov 2020 18:03:08

US3662101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

Have you been exposed to someone with 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 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-17T13:02:56', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a037d762-49d7-4d59-be48-5605fb556160'	System	17 Nov 2020 18:03:08
User entered 'No (N)'	System	17 Nov 2020 18:03:08

US3662101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-17T13:03:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a037d762-49d7-4d59-be48-5605fb556160' User entered '17 Nov 2020 13:03:06'	System	17 Nov 2020 18:03:08
	System	17 Nov 2020 18:03:08

US3662101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 13:48:33

US3662101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:45:44
Data entry locked.	System	16 Sep 2020 13:48:33
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 13:48:33

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-23T05:25:10', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7f88c755-0ee3-4597-a1dc-d769f27d6c71'	System	23 Nov 2020 10:25:36
User entered 'No (N)'	System	23 Nov 2020 10:25:36

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-23T05:25:22', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7f88c755-0ee3-4597-a1dc-d769f27d6c71'	System	23 Nov 2020 10:25:36
User entered 'No (N)'	System	23 Nov 2020 10:25:36

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-23T05:25:32', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7f88c755-0ee3-4597-a1dc-d769f27d6c71' User entered '23 Nov 2020 05:25:32'	System	23 Nov 2020 10:25:36
	System	23 Nov 2020 10:25:36

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-27T08:05:30', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e0123094-eea7-479b-8416-98932e6f349a' User entered 'No (N)'	System	27 Nov 2020 13:05:47

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-27T08:05:40', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e0123094-eea7-479b-8416-98932e6f349a' User entered 'No (N)'	System	27 Nov 2020 13:05:47

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-11-27T08:05:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'e0123094-eea7-479b-8416-98932e6f349a' User entered '27 Nov 2020 08:05:46'	System	27 Nov 2020 13:05:47
	System	27 Nov 2020 13:05:47

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-04T10:24:45', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3c56062b-0c3c-4752-9d2f-7b134e4260b0' User entered 'No (N)'	System	04 Dec 2020 15:25:02
	System	04 Dec 2020 15:25:02

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-04T10:24:53', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3c56062b-0c3c-4752-9d2f-7b134e4260b0'	System	04 Dec 2020 15:25:02
User entered 'No (N)'	System	04 Dec 2020 15:25:02

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-04T10:24:59', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3c56062b-0c3c-4752-9d2f-7b134e4260b0' User entered '04 Dec 2020 10:24:59'	System	04 Dec 2020 15:25:02
	System	04 Dec 2020 15:25:02

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-11T10:41:24', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '10fab4bd-6f38-4a63-8808-1174045785c7'	System	11 Dec 2020 15:41:45
User entered 'No (N)'	System	11 Dec 2020 15:41:45

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-11T10:41:33', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '10fab4bd-6f38-4a63-8808-1174045785c7'	System	11 Dec 2020 15:41:45
User entered 'No (N)'	System	11 Dec 2020 15:41:45

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-11T10:41:39', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '10fab4bd-6f38-4a63-8808-1174045785c7' User entered '11 Dec 2020 10:41:39'	System	11 Dec 2020 15:41:45
	System	11 Dec 2020 15:41:45

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-18T09:08:36', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1863277a-eeb0-40ec-818b-8d052661bc24'	System	18 Dec 2020 14:09:28
User entered 'Yes (Y)'	System	18 Dec 2020 14:09:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-18T09:08:44', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1863277a-eeb0-40ec-818b-8d052661bc24'	System	18 Dec 2020 14:09:28
User entered 'No (N)'	System	18 Dec 2020 14:09:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-18T09:08:51', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1863277a-eeb0-40ec-818b-8d052661bc24'	System	18 Dec 2020 14:09:28
User entered 'No (N)'	System	18 Dec 2020 14:09:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-18T09:09:06', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1863277a-eeb0-40ec-818b-8d052661bc24'	System	18 Dec 2020 14:09:28
User entered 'No (N)'	System	18 Dec 2020 14:09:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-18T09:09:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '1863277a-eeb0-40ec-818b-8d052661bc24'	System	18 Dec 2020 14:09:28
User entered '18 Dec 2020 09:09:25'	System	18 Dec 2020 14:09:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-25T07:36:36', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0c2ed80e-4bf3-49c9-a781-4b3127828d8d' User entered 'No (N)'	System	25 Dec 2020 12:37:02
	System	25 Dec 2020 12:37:02

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-25T07:36:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0c2ed80e-4bf3-49c9-a781-4b3127828d8d' User entered 'No (N)'	System	25 Dec 2020 12:37:02
	System	25 Dec 2020 12:37:02

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2020-12-25T07:36:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '0c2ed80e-4bf3-49c9-a781-4b3127828d8d' User entered '25 Dec 2020 07:36:58'	System	25 Dec 2020 12:37:02
	System	25 Dec 2020 12:37:02

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-01T10:14:14', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '47537058-6423-454c-8e90-070628032eec'	System	01 Jan 2021 15:15:00
User entered 'No (N)'	System	01 Jan 2021 15:15:00

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-01T10:14:42', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '47537058-6423-454c-8e90-070628032eec'	System	01 Jan 2021 15:15:00
User entered 'No (N)'	System	01 Jan 2021 15:15:00

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-01T10:14:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '47537058-6423-454c-8e90-070628032eec' User entered '01 Jan 2021 10:14:58'	System	01 Jan 2021 15:15:00

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-08T09:52:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a725d812-eaae-4bf0-a077-8510aeac0bbf' User entered 'No (N)'	System	08 Jan 2021 14:52:43

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-08T09:52:35', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a725d812-eaae-4bf0-a077-8510aeac0bbf' User entered 'No (N)'	System	08 Jan 2021 14:52:43

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-08T09:52:39', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'a725d812-eaae-4bf0-a077-8510aeac0bbf' User entered '08 Jan 2021 09:52:39'	System	08 Jan 2021 14:52:43
	System	08 Jan 2021 14:52:43

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-15T06:48:25', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '39d9e408-dddb-40fc-93e1-5082a7739f8a' User entered 'No (N)'	System	15 Jan 2021 11:48:51
	System	15 Jan 2021 11:48:51

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-15T06:48:36', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '39d9e408-dddb-40fc-93e1-5082a7739f8a' User entered 'No (N)'	System	15 Jan 2021 11:48:51

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-15T06:48:46', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '39d9e408-dddb-40fc-93e1-5082a7739f8a' User entered '15 Jan 2021 06:48:46'	System	15 Jan 2021 11:48:51
	System	15 Jan 2021 11:48:51

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-22T09:34:41', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd9246be0-20b5-43a5-baaf-e1a5b87afdbd'	System	22 Jan 2021 14:34:57
User entered 'No (N)'	System	22 Jan 2021 14:34:57

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-22T09:34:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd9246be0-20b5-43a5-baaf-e1a5b87afdbd'	System	22 Jan 2021 14:34:57
User entered 'No (N)'	System	22 Jan 2021 14:34:57

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-22T09:34:54', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd9246be0-20b5-43a5-baaf-e1a5b87afdbd' User entered '22 Jan 2021 09:34:54'	System	22 Jan 2021 14:34:57
	System	22 Jan 2021 14:34:57

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-30T12:56:43', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f818f0bd-bb78-450f-bfea-04183ba4d1ae' User entered 'No (N)'	System	30 Jan 2021 17:56:56
	System	30 Jan 2021 17:56:56

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-30T12:56:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f818f0bd-bb78-450f-bfea-04183ba4d1ae' User entered 'No (N)'	System	30 Jan 2021 17:56:56

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-01-30T12:56:52', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'f818f0bd-bb78-450f-bfea-04183ba4d1ae' User entered '30 Jan 2021 12:56:52'	System	30 Jan 2021 17:56:56
	System	30 Jan 2021 17:56:56

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-07T12:01:28', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'aff53a6e-3384-457b-9389-2b9fc95da944'	System	07 Feb 2021 17:03:53
User entered 'No (N)'	System	07 Feb 2021 17:03:53

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-07T12:01:37', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'aff53a6e-3384-457b-9389-2b9fc95da944'	System	07 Feb 2021 17:03:53
User entered 'No (N)'	System	07 Feb 2021 17:03:53

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-07T12:01:48', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'aff53a6e-3384-457b-9389-2b9fc95da944'	System	07 Feb 2021 17:03:53
User entered '07 Feb 2021 12:01:48'	System	07 Feb 2021 17:03:53

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-12T05:01:02', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '5794228f-f302-4538-9a36-fa2056a72104'	System	12 Feb 2021 10:01:19
User entered 'No (N)'	System	12 Feb 2021 10:01:19

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-12T05:01:09', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '5794228f-f302-4538-9a36-fa2056a72104'	System	12 Feb 2021 10:01:19
User entered 'No (N)'	System	12 Feb 2021 10:01:19

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-12T05:01:17', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '5794228f-f302-4538-9a36-fa2056a72104' User entered '12 Feb 2021 05:01:17'	System	12 Feb 2021 10:01:19
	System	12 Feb 2021 10:01:19

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-19T07:08:58', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '88526823-c1ba-4cf6-94e5-fbe32a814a54'	System	19 Feb 2021 12:10:03
User entered 'Yes (Y)'	System	19 Feb 2021 12:10:03

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-19T07:09:04', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '88526823-c1ba-4cf6-94e5-fbe32a814a54'	System	19 Feb 2021 12:10:03
User entered 'No (N)'	System	19 Feb 2021 12:10:03

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-19T07:09:17', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '88526823-c1ba-4cf6-94e5-fbe32a814a54'	System	19 Feb 2021 12:10:03
User entered 'No (N)'	System	19 Feb 2021 12:10:03

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-19T07:09:26', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '88526823-c1ba-4cf6-94e5-fbe32a814a54'	System	19 Feb 2021 12:10:03
User entered 'Yes (Y)'	System	19 Feb 2021 12:10:03

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Please 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-19T07:09:39', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '88526823-c1ba-4cf6-94e5-fbe32a814a54'	System	19 Feb 2021 12:10:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Feb 2021 12:10:03

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-19T07:09:53', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '88526823-c1ba-4cf6-94e5-fbe32a814a54' User entered '19 Feb 2021 07:09:53'	System	19 Feb 2021 12:10:03
	System	19 Feb 2021 12:10:03

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-26T09:44:27-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2a40c3c4-d9bf-4238-8e58-84fc0032c7f8'	System	26 Feb 2021 14:45:16
User entered 'Yes (Y)'	System	26 Feb 2021 14:45:16

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-26T09:44:35-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2a40c3c4-d9bf-4238-8e58-84fc0032c7f8'	System	26 Feb 2021 14:45:16
User entered 'No (N)'	System	26 Feb 2021 14:45:16

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-26T09:44:43-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2a40c3c4-d9bf-4238-8e58-84fc0032c7f8'	System	26 Feb 2021 14:45:16
User entered 'No (N)'	System	26 Feb 2021 14:45:16

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-26T09:44:50-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2a40c3c4-d9bf-4238-8e58-84fc0032c7f8'	System	26 Feb 2021 14:45:16
User entered 'Yes (Y)'	System	26 Feb 2021 14:45:16

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Please 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-26T09:45:00-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2a40c3c4-d9bf-4238-8e58-84fc0032c7f8'	System	26 Feb 2021 14:45:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Feb 2021 14:45:16

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-02-26T09:45:04-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2a40c3c4-d9bf-4238-8e58-84fc0032c7f8'	System	26 Feb 2021 14:45:16
User entered '26 Feb 2021 14:45:04'	System	26 Feb 2021 14:45:16

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-05T06:43:08-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '58ef66ee-3ee6-4400-991f-f92a5dea9af3'	System	05 Mar 2021 11:43:20
User entered 'No (N)'	System	05 Mar 2021 11:43:20

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-05T06:43:11-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '58ef66ee-3ee6-4400-991f-f92a5dea9af3'	System	05 Mar 2021 11:43:20
User entered 'No (N)'	System	05 Mar 2021 11:43:20

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-05T06:43:18-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '58ef66ee-3ee6-4400-991f-f92a5dea9af3' User entered '05 Mar 2021 06:43:18'	System	05 Mar 2021 11:43:20
	System	05 Mar 2021 11:43:20

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-14T12:31:06-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '72272e53-7173-48f2-8b7f-fba8cc687424'	System	14 Mar 2021 16:31:28
User entered 'No (N)'	System	14 Mar 2021 16:31:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-14T12:31:14-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '72272e53-7173-48f2-8b7f-fba8cc687424'	System	14 Mar 2021 16:31:28
User entered 'No (N)'	System	14 Mar 2021 16:31:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-14T12:31:24-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '72272e53-7173-48f2-8b7f-fba8cc687424' User entered '14 Mar 2021 12:31:24'	System	14 Mar 2021 16:31:28
	System	14 Mar 2021 16:31:28

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-20T09:48:21-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '194a14d3-aa10-4faf-b519-32afe07ed437'	System	20 Mar 2021 13:48:39
User entered 'No (N)'	System	20 Mar 2021 13:48:39

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-20T09:48:28-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '194a14d3-aa10-4faf-b519-32afe07ed437'	System	20 Mar 2021 13:48:39
User entered 'No (N)'	System	20 Mar 2021 13:48:39

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-20T09:48:36-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '194a14d3-aa10-4faf-b519-32afe07ed437'	System	20 Mar 2021 13:48:39
User entered '20 Mar 2021 09:48:36'	System	20 Mar 2021 13:48:39

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-26T09:39:52-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd8ca02e8-de9d-4e6d-aa55-ae0fb70cd4e1'	System	26 Mar 2021 13:40:10
User entered 'No (N)'	System	26 Mar 2021 13:40:10

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-26T09:39:58-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd8ca02e8-de9d-4e6d-aa55-ae0fb70cd4e1'	System	26 Mar 2021 13:40:10
User entered 'No (N)'	System	26 Mar 2021 13:40:10

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-26T09:40:06-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd8ca02e8-de9d-4e6d-aa55-ae0fb70cd4e1'	System	26 Mar 2021 13:40:10
User entered '26 Mar 2021 09:40:06'	System	26 Mar 2021 13:40:10

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-04T12:00:54-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '76820c25-93a8-4059-a7d6-77d032e0adb7'	System	04 Apr 2021 16:02:40
User entered 'No (N)'	System	04 Apr 2021 16:02:40

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-04T12:01:03-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '76820c25-93a8-4059-a7d6-77d032e0adb7'	System	04 Apr 2021 16:02:40
User entered 'No (N)'	System	04 Apr 2021 16:02:40

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-04T12:01:11-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '76820c25-93a8-4059-a7d6-77d032e0adb7'	System	04 Apr 2021 16:02:40
User entered '04 Apr 2021 12:01:11'	System	04 Apr 2021 16:02:40

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-10T18:56:52-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3f9abf6e-e1ae-4b29-a88a-cc8bee4a6bc7'	System	10 Apr 2021 22:57:11
User entered 'No (N)'	System	10 Apr 2021 22:57:11

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-10T18:57:02-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3f9abf6e-e1ae-4b29-a88a-cc8bee4a6bc7'	System	10 Apr 2021 22:57:11
User entered 'No (N)'	System	10 Apr 2021 22:57:11

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-10T18:57:08-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '3f9abf6e-e1ae-4b29-a88a-cc8bee4a6bc7'	System	10 Apr 2021 22:57:11
User entered '10 Apr 2021 18:57:08'	System	10 Apr 2021 22:57:11

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-16T07:54:23-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7adfb102-c8a8-4ddf-9ec7-967516e38885'	System	16 Apr 2021 11:54:33
User entered 'No (N)'	System	16 Apr 2021 11:54:33

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-16T07:54:26-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7adfb102-c8a8-4ddf-9ec7-967516e38885'	System	16 Apr 2021 11:54:33
User entered 'No (N)'	System	16 Apr 2021 11:54:33

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-16T07:54:31-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '7adfb102-c8a8-4ddf-9ec7-967516e38885'	System	16 Apr 2021 11:54:33
User entered '16 Apr 2021 07:54:31'	System	16 Apr 2021 11:54:33

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-23T05:21:42-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd004a801-0f21-4666-bdc2-c9124f2b4f92'	System	23 Apr 2021 09:21:56
User entered 'No (N)'	System	23 Apr 2021 09:21:56

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-23T05:21:46-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd004a801-0f21-4666-bdc2-c9124f2b4f92'	System	23 Apr 2021 09:21:56
User entered 'No (N)'	System	23 Apr 2021 09:21:56

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-23T05:21:52-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'd004a801-0f21-4666-bdc2-c9124f2b4f92'	System	23 Apr 2021 09:21:56
User entered '23 Apr 2021 05:21:52'	System	23 Apr 2021 09:21:56

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-30T06:30:40-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2b1b9ed8-ce38-45a1-81b7-a57229cbce00'	System	30 Apr 2021 10:30:52
User entered 'No (N)'	System	30 Apr 2021 10:30:52

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Have you been exposed to someone with 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 (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-30T06:30:46-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2b1b9ed8-ce38-45a1-81b7-a57229cbce00' User entered 'No (N)'	System	30 Apr 2021 10:30:52

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-04-30T06:30:49-04:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: '2b1b9ed8-ce38-45a1-81b7-a57229cbce00'	System	30 Apr 2021 10:30:52
User entered '30 Apr 2021 06:30:49'	System	30 Apr 2021 10:30:52

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 08:51:04

US3662101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:51:04
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 08:51:04

US3662101

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:23:56

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 01:45:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-05T07:36:01-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'b05f8cd1-0024-4c64-a4a7-7639423e7f8b' User entered 'No (N)'	System	05 Mar 2021 12:36:08
	System	05 Mar 2021 12:36:08

US3662101

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:23:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:45:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EBA8FA7C-6C38-4397-B9B7-10C04DA6BA88)', Time: '2021-03-05T07:36:05-05:00', User OID: 'PatientReportedOutcome (US3662101)', ODM File OID: 'b05f8cd1-0024-4c64-a4a7-7639423e7f8b' User entered '05 Mar 2021 07:36:05'	System	05 Mar 2021 12:36:08
	System	05 Mar 2021 12:36:08

US3662101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Dec 2020 15:56:40

US3662101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '8 Dec 2020'	Angela Snyder (b) (4)	08 Dec 2020 15:56:40

US3662101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	08 Dec 2020 15:56:40

US3662101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Angela Snyder (b) (4)	08 Dec 2020 15:56:40

US3662101

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Dec 2020 15:56:45

US3662101

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:34:29
User entered '1'	System	08 Dec 2020 15:56:45

US3662101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 15:06:45

US3662101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 15:06:45

US3662101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	13 Jan 2021 15:06:45

US3662101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Angela Snyder (b) (4)	13 Jan 2021 15:06:45

US3662101

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 15:07:07

US3662101

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User entered '1'	System	13 Jan 2021 15:07:07

US3662101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Feb 2021 16:38:12

US3662101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '11 Feb 2021'	Angela Snyder (b) (4)	11 Feb 2021 16:38:12

US3662101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	11 Feb 2021 16:38:12

US3662101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Angela Snyder (b) (4)	11 Feb 2021 16:38:12

US3662101

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Feb 2021 16:38:18

US3662101

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User entered '1'	System	11 Feb 2021 16:38:18

US3662101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Mar 2021 15:28:31

US3662101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '15 Mar 2021'	Angela Snyder (b) (4)	15 Mar 2021 15:28:31

US3662101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	15 Mar 2021 15:28:31

US3662101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:23:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Angela Snyder (b) (4)	15 Mar 2021 15:28:31

US3662101

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Mar 2021 15:28:36

US3662101

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:23:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:15
User entered '1'	System	15 Mar 2021 15:28:36

US3662101

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

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 15:05:35

US3662101

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

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 15:05:35

US3662101

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

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[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 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	13 Jan 2021 15:05:35

US3662101

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

Form: Visit Date

Generated On: 10 Jun 2021 09:23:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 15:05:35

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 15:05:48

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	09 Apr 2021 12:22:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:08:45

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 15:05:48

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
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 07:21:58
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 12:22:20
User entered 'Amendment 6 or later (Amendment 6 or later)'	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 12:22:06
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 07:14:32
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:08:45

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 15:05:48

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4)	13 Jan 2021 15:05:48

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 04:47:53
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4)	13 Jan 2021 15:05:48
	(b) (4)	

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 04:47:53
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4)	13 Jan 2021 15:05:48
	(b) (4)	

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Angela Snyder (b) (4)	13 Jan 2021 15:05:48

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	13 Jan 2021 15:05:48

US3662101

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

Form: Unblinding

Generated On: 10 Jun 2021 09:23:56

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered empty.	System	13 Jan 2021 15:05:48

US3662101

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 15:06:14

US3662101

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 15:06:14

US3662101

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '11:00'	Angela Snyder (b) (4)	13 Jan 2021 15:06:14

US3662101

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:23:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '12 Jan 2021 11:00'	System	13 Jan 2021 15:06:14

US3662101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:23:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 15:06:30

US3662101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 15:06:30

US3662101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:23:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '10:05'	Angela Snyder (b) (4)	13 Jan 2021 15:06:30

US3662101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:23:56

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:54
User entered '12 Jan 2021 10:05'	System	13 Jan 2021 15:06:30

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:23:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Angela Snyder (b) (4)	22 Feb 2021 17:18:10

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:44:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:09
User entered		
'USA-US088-2021-mRNA-1273-P301000010'	System	12 Apr 2021 13:07:53
User entered 'New'	(b) (4), (b) (6)	12 Apr 2021 13:07:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Adverse event](#)

Audit	User	Time (GMT)
User closed query ' Please consider whether elevated blood pressure meets AE/SAE reporting criteria and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:28
Query ' Please consider whether elevated blood pressure meets AE/SAE reporting criteria and update report if appropriate.' answered with 'see log line 5, which was entered prior to this query. ' (Site from Safety).	michelle saemann (b) (4)	19 Apr 2021 14:51:44
User opened query ' Please consider whether elevated blood pressure meets AE/SAE reporting criteria and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:57:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Salivary gland neoplasms malignant, PT: Salivary gland cancer stage IV, LLT: Malignant neoplasm of parotid gland stage IV - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 13:11:47
Data point term sent to Coder	(b) (4)	
User entered 'malignant neoplasm of parotid gland stage iva'	System	08 Apr 2021 12:12:33
	Angela Snyder (b) (4)	08 Apr 2021 12:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '17 Feb 2021'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:29:01
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:37:13
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:53:27
User entered empty.	System	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:30:57
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
Signature has been broken.	michelle saemann (b) (4)	09 Apr 2021 18:19:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
reason for change: Data Entry Error	michelle saemann (b) (4)	09 Apr 2021 18:19:29
User signature succeeded.	(b) (4)	
	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:44:44
Signature has been broken.	Michelle Saemann (b) (4)	09 Apr 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Saemann (b) (4)	09 Apr 2021 18:19:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:44:44
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)	12 Apr 2021 07:22:48
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 ' Pt. still in hospital so no d/c date available. ' (Site from System).	michelle saemann (b) (4)	09 Apr 2021 18:22:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		09 Apr 2021 18:21:14
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		09 Apr 2021 18:21:14
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	09 Apr 2021 18:21:14
Signature has been broken.	michelle saemann (b) (4)	09 Apr 2021 18:21:14
User entered '1' reason for change: Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	09 Apr 2021 18:21:14
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	
User signature succeeded.	System	09 Apr 2021 18:19:29
	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 12:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm when the subject was in SICU for elevated blood pressure. Was it during the same time when the subject was hospitalized on 08 Apr 2021?' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:33
Query 'PV Query: Please confirm when the subject was in SICU for elevated blood pressure. Was it during the same time when the subject was hospitalized on 08 Apr 2021?' answered with 'yes, elevated blood pressure was post surgery' (Site from Safety).	michelle saemann (b) (4)	19 Apr 2021 15:07:38
User opened query 'PV Query: Please confirm when the subject was in SICU for elevated blood pressure. Was it during the same time when the subject was hospitalized on 08 Apr 2021?' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:51:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
Signature has been broken.	michelle saemann (b) (4)	09 Apr 2021 18:19:29
User entered '08 Apr 2021' reason for change: Data Entry Error	michelle saemann (b) (4)	09 Apr 2021 18:19:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:09:30
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:34
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	michelle saemann (b) (4)	19 Apr 2021 15:08:32
DataPoint Un-verified.	michelle saemann (b) (4)	19 Apr 2021 15:08:10
Signature has been broken.	michelle saemann (b) (4)	19 Apr 2021 15:08:10
User entered '11 Apr 2021' reason for change: Data Entry Error	michelle saemann (b) (4)	19 Apr 2021 15:08:10
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:52:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:44:44
Signature has been broken.	Michelle Saemann (b) (4)	09 Apr 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Michelle Saemann (b) (4)	09 Apr 2021 18:19:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:44:44
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	09 Apr 2021 18:21:14
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	09 Apr 2021 18:21:14
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	09 Apr 2021 18:19:29
Signature has been broken.	michelle saemann (b) (4)	09 Apr 2021 18:19:29
User entered '1' reason for change: Data Entry Error	(b) (4) michelle saemann (b) (4)	09 Apr 2021 18:19:29
User signature succeeded.	(b) (4) Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:44:44
Signature has been broken.	Michelle Saemann (b) (4)	09 Apr 2021 18:19:29
User entered '1' reason for change: Data Entry Error	(b) (4) Michelle Saemann (b) (4)	09 Apr 2021 18:19:29
User signature succeeded.	(b) (4) Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '1'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '1'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:54:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:11:48

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify whether subject has any risk factors for salivary gland cancer.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:47
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:45
User closed query 'PV Query: Did the subject have a medical history of parotid cancer? Was the SAE considered a worsening of the subject's medical history of parotid cancer? Was the subject hospitalized due to worsening of the event or any other therapeutic procedure.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:43
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:42
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:40
User closed query 'PV Query: Please confirm when the procedures of parotidectomy, left-sided neck dissection, submental island flap for left sided malignant neck mass, partial L 7th nerve resection resulting in expected palsy disposition were performed.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:34:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'sent via email on 4/19/21 @ 11:24. Biopsy results pending. ' (Site from Safety).	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 15:25:42
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'see med log and con procedure folder' (Site from Safety).	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 15:13:47
Query 'PV Query: Did the subject have a medical history of parotid cancer? Was the SAE considered a worsening of the subject's medical history of parotid cancer? Was the subject hospitalized due to worsening of the event or any other therapeutic procedure.' answered with 'No medical history of parotid CA. Not worsening but was admitted for surgical procedure so added as SAE per PI. ' (Site from Safety).	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 15:13:13
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 'Had preop test done on 4/2/21 which was negative' (Site from Safety).	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 15:11:18
Query 'PV Query: Please clarify whether subject has any risk factors for salivary gland cancer.' answered with 'no known risk factors' (Site from Safety).	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 11:53:13
Query 'PV Query: Please confirm when the procedures of parotidectomy, left-sided neck dissection, submental island flap for left sided malignant neck mass, partial L 7th nerve resection resulting in expected palsy disposition were performed.' answered with 'This is on the con-procedure form. ' (Site from Safety).	michelle saemann (b) (4)	(b) (4) 19 Apr 2021 11:48:17

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify whether subject has any risk factors for salivary gland cancer.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:57:01
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:56:04
User opened query 'PV Query: Did the subject have a medical history of parotid cancer? Was the SAE considered a worsening of the subject's medical history of parotid cancer? Was the subject hospitalized due to worsening of the event or any other therapeutic procedure.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:54:40
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:53:09
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)	16 Apr 2021 20:51:49
User opened query 'PV Query: Please confirm when the procedures of parotidectomy, left-sided neck dissection, submental island flap for left sided malignant neck mass, partial L 7th nerve resection resulting in expected palsy disposition were performed.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 20:50:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:44
Signature has been broken.	michelle saemann (b) (4)	09 Apr 2021 18:19:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'male with a cancer of the parotid gland, S/p parotidectomy, left-sided neck dissection, and submental island flap for left-sided malignant neck mass, partial L 7th nerve resection resulting in expected palsy DISPOSITION: SICU for elevated BP, likely floor in AM Cardiovascular - Home blood pressure meds restarted - Holding anticoagulation - Arterial line per SICU' reason for change: Data Entry Error	michelle saemann (b) (4)	(b) (4) 09 Apr 2021 18:19:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	(b) (4) 08 Apr 2021 21:54:25
User entered empty.	Angela Snyder (b) (4)	(b) (4) 08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:19:29
User entered '0'	System	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 12:11:48

US3662101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:23:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:19:29

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypomagnesaemia, LLT: Hypomagnesemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Apr 2021 16:06:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 16:06:51
Data point term sent to Coder	System	15 Apr 2021 16:05:53
User entered 'hypomagnesemia'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	15 Apr 2021 16:07:27
User entered '1'	(b) (4) Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '1' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	15 Apr 2021 16:07:27
User entered '0'	(b) (4) Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:23:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:04:54

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Facial cranial nerve disorders, PT: Facial paralysis, LLT: Facial palsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:34:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:34:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
Data point term sent to Coder	System	15 Apr 2021 16:05:53
User entered 'left facial nerve palsy secondary to surgical procedure'	Angela Snyder (b) (4) (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 16:05:57
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	15 Apr 2021 16:05:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Apr 2021 16:05:50
	Angela Snyder (b) (4)	15 Apr 2021 16:05:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '1'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:05:50

US3662101

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:23:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (4)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:05:50

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Folder: Adverse Events

Form: Adverse Events (5)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 09:18:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 09:18:59
Data point term sent to Coder	System	19 Apr 2021 14:50:41
Coding entries removed.	michelle saemann (b) (4) (b) (4)	19 Apr 2021 14:50:20
Signature has been broken.	michelle saemann (b) (4) (b) (4)	19 Apr 2021 14:50:20
User entered 'ELEVATED Blood pressure POST SURGERY' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	19 Apr 2021 14:50:20
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Elevated BP - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:35:38
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 11:35:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
Data point term sent to Coder	System	15 Apr 2021 16:08:00
User entered 'elevated bp post surgery'	Angela Snyder (b) (4) (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '10 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Form: Adverse Events (5)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:07:07

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Grade 3/Severe (Grade 3/Severe)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '1'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:23:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:07:07

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:20:27
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 11:20:27
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
Data point term sent to Coder	System	15 Apr 2021 16:09:00
User entered 'bradycardia during surgery'	Angela Snyder (b) (4) (b) (4)	15 Apr 2021 16:08:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '1'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 16:08:22

US3662101

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:23:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:08:22

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:23:56

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:22:32

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 14:24:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:24:35
Data point term sent to Coder	System	17 Sep 2020 14:23:36
User entered 'CALCIUM'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Brenda Miller (b) (4)	01 Nov 2020 13:54:00
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'DIETARY SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
Signature has been broken.	(b) (4)	
	Angela Snyder (b) (4)	16 Apr 2021 11:15:02
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 03:46:07
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'done' (Site from DM).	MaKayla Bishop (b) (4)	22 Dec 2020 16:23:36
	(b) (4)	
User entered '1200' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	22 Dec 2020 16:23:30
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 10:29:53
User entered '1220'	Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
	(b) (4)	
Signature has been broken.	Angela Snyder (b) (4)	16 Apr 2021 11:16:08
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
Signature has been broken.	(b) (4)	
	Angela Snyder (b) (4)	16 Apr 2021 11:15:25
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jun 2020'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:23:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:23:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:25:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:25:36
Data point term sent to Coder	System	17 Sep 2020 14:24:37
User entered 'CIALIS'	Brenda Miller (b) (4)	17 Sep 2020 14:24:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'ENLARGED PROSTATE'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '10'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2019'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:24:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:24:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:24:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:25:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:25:36
Data point term sent to Coder	System	17 Sep 2020 14:24:37
User entered 'FLOMAX'	Brenda Miller (b) (4)	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'ENLARGED PROSTATE'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:31:38
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Medication dose updated ' (Site from DM).	Angela Snyder (b) (4) (b) (4)	02 Dec 2020 19:24:56
User entered '0.4' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	02 Dec 2020 19:24:33
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:33:31
User entered '10'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2019'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:24:35
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:24:35

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Dec 2020 21:23:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:23:50
Data point term sent to Coder	System	02 Dec 2020 18:42:15
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	02 Dec 2020 18:41:18
User entered 'TESTOSTERONE GEL 1.62 %' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	02 Dec 2020 18:41:18
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 09:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 09:55:43
Data point term sent to Coder	System	17 Sep 2020 14:26:39
User entered 'TESTOSTERONE'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'ENLARGED PROSTATE'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User closed query 'Per DM CLR: Please review the dose and unit to record the actual dose given as it seems to be the drug preparation/concentration. Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:34:09
Query 'Per DM CLR: Please review the dose and unit to record the actual dose given as it seems to be the drug preparation/concentration. Update as appropriate, otherwise clarify. ' answered with 'DONE ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	02 Dec 2020 18:41:24
User entered '20.25' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	02 Dec 2020 18:41:18
User opened query 'Per DM CLR: Please review the dose and unit to record the actual dose given as it seems to be the drug preparation/concentration. Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:33:03
User entered '2'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) MaKayla Bishop (b) (4)	02 Dec 2020 18:41:18
User entered 'Other (OTHER)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty; reason for change Data Entry Error	(b) (4) MaKayla Bishop (b) (4)	02 Dec 2020 18:41:18
User entered 'mg/mL'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Topical (TOPICAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2019'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:25:39
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:25:39

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:27:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:27:43
Data point term sent to Coder	System	17 Sep 2020 14:26:40
User entered 'JANUMET'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'TYPE 2 DIABETES'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '50-1000'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'twice daily (BID)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2015'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
Signature has been broken.	Angela Snyder (b) (4)	08 Apr 2021 12:13:28
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Apr 2021 12:13:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
Signature has been broken.	Angela Snyder (b) (4)	08 Apr 2021 12:13:28
User entered '21 Jan 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Apr 2021 12:13:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User entered '2'	System	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User entered '1'	System	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:09:02
User entered '804 (804)'	System	17 Sep 2020 14:26:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
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)	17 Sep 2020 14:28:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:28:36
Data point term sent to Coder	System	17 Sep 2020 14:27:41
User entered 'IBUPROFEN'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'MUSCLE SORENESS'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '800'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'as needed (PRN)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2010'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:01
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 14:27:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 14:27:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 14:27:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 14:28:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:28:36
Data point term sent to Coder	System	17 Sep 2020 14:27:43
User entered 'EZETIMIBE'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'HIGH CHOLESTEROL'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:38:23
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Medication dosage updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	02 Dec 2020 19:25:49
User entered '10' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	02 Dec 2020 19:25:34
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:32:35
User entered '100'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:27:37
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:27:37
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:37
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '01 Jul 2008'	Brenda Miller (b) (4)	17 Sep 2020 14:27:37
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:27:37
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:27:37
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:27:37
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:27:37

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:29:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:29:36
Data point term sent to Coder	System	17 Sep 2020 14:28:46
User entered 'ASPIRIN'	Brenda Miller (b) (4)	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'CORONARY ARTERY DISEASE'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '81'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '01 Jul 2003'	Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:17
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:28:17

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 14:30:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:30:43
Data point term sent to Coder	System	17 Sep 2020 14:29:52
User entered 'ATORVASTATINE CALCIUM'	Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'HIGH CHOLESTEROL'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '80'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2003'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:28:59
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:28:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
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.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 14:30:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 14:30:42
Data point term sent to Coder User entered 'LOSARTAN'	System Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:29:53 17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'HYPERTENSION'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '100'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '01 Jul 2003'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:29:41
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 14:29:41

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
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)	22 Oct 2020 17:46:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:46:39
Data point term sent to Coder User entered 'IBUPROFEN'	System Brenda Miller (b) (4) (b) (4)	22 Oct 2020 17:46:04 22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 03:47:38
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'reported on eduary ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	22 Dec 2020 13:53:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 10:30:39
User entered 'HEADACHE'	Brenda Miller (b) (4) (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '400'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'once (ONCE)'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '17 Oct 2020'	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '17 Oct 2020'	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User entered empty.	System	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User entered empty.	System	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:07:23
User entered empty.	System	22 Oct 2020 17:45:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
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)	22 Oct 2020 17:51:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:51:41
Data point term sent to Coder User entered 'IBUPROFEN'	System Brenda Miller (b) (4) (b) (4)	22 Oct 2020 17:50:11 22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 03:49:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'reported on eduary ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	22 Dec 2020 13:52:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 10:30:55
User entered 'HEADACHE'	Brenda Miller (b) (4) (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '800'	Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'mg (mg)'	Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	Brenda Miller (b) (4)	03 Nov 2020 21:41:11
User entered 'once (ONCE)'	(b) (4)	
	Brenda Miller (b) (4)	22 Oct 2020 17:49:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '14 Oct 2020'	(b) (4) Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '0'	Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'No (N)'	Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	03 Nov 2020 21:41:11
User entered '14 Oct 2020'	(b) (4)	
	Brenda Miller (b) (4)	22 Oct 2020 17:49:27
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User entered empty.	System	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User entered empty.	System	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:26
User entered empty.	System	22 Oct 2020 17:49:27

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
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.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 15:59:54
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 Dec 2020 15:59:54
Data point term sent to Coder	System	08 Dec 2020 15:58:45
User entered 'HYDROCHLOROTHIAZIDE'	Angela Snyder (b) (4) (b) (4)	08 Dec 2020 15:58:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'HYPERTENSION'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '12.5'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '7 Dec 2020'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Dec 2020 15:58:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 15:58:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 15:58:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 15:58:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 12:33:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:33:38
Data point term sent to Coder	System	08 Apr 2021 12:19:36
User entered 'metaformin'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:18:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'type 2 diabetes'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:18:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered '1000'	Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'twice daily (BID)'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '22 Jan 2021'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Apr 2021 12:18:51
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:18:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 12:18:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 12:18:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 12:18:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
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: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:33:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:33:38
Data point term sent to Coder	System	08 Apr 2021 12:20:37
User entered 'dexamethasone'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '8'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
User entered empty.	System	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
User entered empty.	System	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:55:51
User entered empty.	System	08 Apr 2021 12:20:28

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:34:42
Data point term sent to Coder	System	08 Apr 2021 12:31:46
Data point term sent to Coder	System	08 Apr 2021 12:21:38
User entered 'ephedrine'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '10'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Apr 2021 12:31:15
User entered 'Rectal (RECTAL)'	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 12:21:07
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
User entered empty.	System	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
User entered empty.	System	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:56:31
User entered empty.	System	08 Apr 2021 12:21:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:34:42
Data point term sent to Coder	System	08 Apr 2021 12:22:40
User entered 'ephedrine'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '5'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:03:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
User entered empty.	System	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
User entered empty.	System	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:24
User entered empty.	System	08 Apr 2021 12:21:47

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
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 12:36:39
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 12:36:39
Data point term sent to Coder	System	08 Apr 2021 12:23:40
User entered 'fentanyl'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '100'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'ug (ug)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
User entered empty.	System	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
User entered empty.	System	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:57:57
User entered empty.	System	08 Apr 2021 12:22:49

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:36:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:36:40
Data point term sent to Coder	System	08 Apr 2021 12:24:41
User entered 'glycopyrrolate'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0.2'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
User entered empty.	System	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
User entered empty.	System	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:58:33
User entered empty.	System	08 Apr 2021 12:23:42

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: EPINEPHRINE HYDROCHLORIDE;LIDOCAINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:35:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:35:43
Data point term sent to Coder	System	08 Apr 2021 12:25:43
User entered 'epinephrine hcl comb; lidocaine hcl 1%-1:100,000'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '2'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mL (mL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
User entered empty.	System	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
User entered empty.	System	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:59:38
User entered empty.	System	08 Apr 2021 12:25:20

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: REMIFENTANIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:31:47
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 12:31:47
Data point term sent to Coder	System	08 Apr 2021 12:26:43
User entered 'remifentanil'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '1'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
User entered empty.	System	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
User entered empty.	System	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:20
User entered empty.	System	08 Apr 2021 12:26:01

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: EPINEPHRINE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:34:42
Data point term sent to Coder	System	08 Apr 2021 12:26:43
User entered 'epinephrine hcl'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:32:49
Signature has been broken.	michelle saemann (b) (4)	13 Apr 2021 18:25:37
User entered '10' reason for change: Data Entry Error	(b) (4) michelle saemann (b) (4)	13 Apr 2021 18:25:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '1'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:32:49
Signature has been broken.	michelle saemann (b) (4)	13 Apr 2021 18:25:37
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) michelle saemann (b) (4)	13 Apr 2021 18:25:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:59:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User closed query 'Per source frequency is BID. Please verify and update as needed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:59:26
Query 'Per source frequency is BID. Please verify and update as needed. ' answered with 'updated' (Site from CRA).	michelle saemann (b) (4)	14 Apr 2021 00:33:37
Signature has been broken.	michelle saemann (b) (4)	14 Apr 2021 00:33:19
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	michelle saemann (b) (4)	14 Apr 2021 00:33:19
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:32:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User opened query 'Per source frequency is BID. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:31:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:26:40
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:32:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
User entered '2'	System	14 Apr 2021 00:33:19
User entered empty.	System	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
User entered '1'	System	14 Apr 2021 00:33:19
User entered empty.	System	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:55
User entered '804 (804)'	System	14 Apr 2021 00:33:19
User entered empty.	System	08 Apr 2021 12:26:40

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: CHOLINE DERIVATIVES, PRODUCT: SUXAMETHONIUM CHLORIDE, PRODUCTSYNONYM: SUCCINYLCHOLINE CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:28:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:28:38
Data point term sent to Coder	System	08 Apr 2021 12:27:44
User entered 'succinylcholine chloride'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '100'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
User entered empty.	System	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
User entered empty.	System	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:03:32
User entered empty.	System	08 Apr 2021 12:27:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:29:49
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 12:29:49
Data point term sent to Coder	System	08 Apr 2021 12:28:45
User entered 'lactated ringers'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '125'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Other (OTHER)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'ml/hr'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
User entered empty.	System	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
User entered empty.	System	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:11
User entered empty.	System	08 Apr 2021 12:28:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: LIDOCAINE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:35:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:35:43
Data point term sent to Coder	System	08 Apr 2021 12:29:45
User entered 'lidocaine hcl'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '100'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 12:29:07
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
User entered empty.	System	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
User entered empty.	System	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:04:54
User entered empty.	System	08 Apr 2021 12:29:07

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
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.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:41:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:41:04
Data point term sent to Coder	System	08 Apr 2021 12:30:46
User entered 'midazolam hcl'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '2'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
User entered empty.	System	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
User entered empty.	System	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:05:51
User entered empty.	System	08 Apr 2021 12:29:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:32:48
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 12:32:48
Data point term sent to Coder	System	08 Apr 2021 12:30:46
User entered 'zofran'	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '4'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mg (mg)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
User entered empty.	System	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
User entered empty.	System	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:55
User entered empty.	System	08 Apr 2021 12:30:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: ULTRAM [TRAMADOL HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 11:16:02
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 11:16:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
Data point term sent to Coder	System	15 Apr 2021 16:43:41
User entered 'ultram'	Angela Snyder (b) (4) (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:05:10
Query 'Per source indication is post operative "pain." Please verify and update as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:05:09
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:04:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User opened query 'Per source indication is post operative "pain." Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:02:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'post operative for left parotidectomy, left neck dissection submental flap nerve resection and nerve graft'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '50'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'four times daily (QID)'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 16:42:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
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)	15 Apr 2021 16:45:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 16:45:49
Data point term sent to Coder	System	15 Apr 2021 16:44:41
User entered 'Tylenol'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:05:31
Query 'Per source indication is post operative "pain." Please verify and update as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:05:29
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:04:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User opened query 'Per source indication is post operative "pain." Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:01:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'post operative for left parotidectomy, left neck dissection submental flap nerve resection and nerve graft'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '975'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '11 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 16:44:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
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)	16 Apr 2021 09:44:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:44:07
Data point term sent to Coder	System	15 Apr 2021 16:46:45
User entered 'senna concentrate'	Angela Snyder (b) (4) (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'constipation prevention'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8.6'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '11 Apr 2021'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 16:46:26

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN ZINC;POLYMYXIN B SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 11:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:22:52
Data point term sent to Coder	System	16 Apr 2021 11:19:06
User entered 'bacitracin zinc; comb; polymyxin b sulfate'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'surgical procedure'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '1000/500'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'units'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Topical (TOPICAL)'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '11 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:18:29

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCODONE HCL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 11:20:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:20:48
Data point term sent to Coder	System	16 Apr 2021 11:20:07
User entered 'oxycodone hcl'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:05:50
Query 'Per source indication is post operative "pain." Please verify and update as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:05:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:04:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User opened query 'Per source indication is post operative "pain." Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:00:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'POST OPERATIVE FOR LEFT PAROTIDECTOMY, LEFT NECK DISSECTION SUBMENTAL FLAP NERVE RESECTION AND NERVE GRAFT'	(b) (4) Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '5'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'as needed (PRN)'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:19:18

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
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)	16 Apr 2021 13:05:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 13:05:51
Data point term sent to Coder	System	16 Apr 2021 11:21:08
User entered 'ibuprofen'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:04
Query 'Per source indication is post operative "pain." Please verify and update as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:04:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User opened query 'Per source indication is post operative "pain." Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:00:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'POST OPERATIVE FOR LEFT PAROTIDECTOMY, LEFT NECK DISSECTION SUBMENTAL FLAP NERVE RESECTION AND NERVE GRAFT'	(b) (4) Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '400'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'three times daily (TID)'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:20:31

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
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)	16 Apr 2021 11:22:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:22:52
Data point term sent to Coder	System	16 Apr 2021 11:22:10
User entered 'hydromorphone hcl'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:06:09
Query 'Per source the indication is post operative "pain." Please verify and update as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:06:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:04:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User opened query 'Per source the indication is post operative "pain." Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:59:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'POST OPERATIVE FOR LEFT PAROTIDECTOMY, LEFT NECK DISSECTION SUBMENTAL FLAP NERVE RESECTION AND NERVE GRAFT'	(b) (4) Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0.5'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'as needed (PRN)'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	(b) (4) Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '9 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:21:33

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
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)	16 Apr 2021 11:24:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:24:09
Data point term sent to Coder	System	16 Apr 2021 11:23:11
User entered 'hydralazine hcl'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'elevated bp post surgery'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '10'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'other (OTHER)'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'every 4-6 hours'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '9 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:22:51

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 16:12:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:12:57
Data point term sent to Coder	System	16 Apr 2021 11:24:11
User entered 'heparin'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'blood clot prevention'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '5000'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'IU (IU)'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'three times daily (TID)'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Subcutaneous (SUBCUTANEOUS)'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '11 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:03:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:23:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: EPINEPHRINE HCL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 11:57:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:57:52
Data point term sent to Coder	System	16 Apr 2021 11:26:12
User entered 'epinephrine hcl'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'bradycardia'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '5'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'ug (ug)'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'once (ONCE)'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:57:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 11:25:52

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:42
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:27:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:27:51
Data point term sent to Coder	System	16 Apr 2021 11:27:12
User entered 'magnesium sulfate'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'hypomagnesemia'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '1'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'g (g)'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '9 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '9 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:26:59

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:11:52
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 13:11:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
Data point term sent to Coder	System	16 Apr 2021 11:29:13
User entered 'insulin lispro; humalog'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'type 3 diabetes mellitus'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'UNK'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 11:28:50
User entered 'Other (OTHER)' reason for change: Data Entry Error	System	16 Apr 2021 11:28:50
User opened query 'Data is required. Please complete.' (Site from System).	Angela Snyder (b) (4)	16 Apr 2021 11:28:50
User entered empty.	(b) (4)	
	System	16 Apr 2021 11:28:34
	Angela Snyder (b) (4)	16 Apr 2021 11:28:34
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	16 Apr 2021 11:28:50
User entered empty.	(b) (4)	
	Angela Snyder (b) (4)	16 Apr 2021 11:28:34
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'three times daily (TID)'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Subcutaneous (SUBCUTANEOUS)'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:41:26
User closed query 'Per source start date is 09Apr2021. Please verify and update EDC if needed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:59:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:49
Query 'Per source start date is 09Apr2021. Please verify and update EDC if needed. ' answered with 'Data updated' (Site from CRA).	Angela Snyder (b) (4) (b) (4)	22 Apr 2021 11:22:40
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	22 Apr 2021 11:22:22
User entered '9 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Apr 2021 11:22:22
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User opened query 'Per source start date is 09Apr2021. Please verify and update EDC if needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:55:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
User entered '8 Apr 2021'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '11 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:56:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:28:34

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
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)	16 Apr 2021 11:30:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 11:30:49
Data point term sent to Coder	System	16 Apr 2021 11:30:14
User entered 'Tylenol'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'POST OPERATIVE FOR LEFT PAROTIDECTOMY, LEFT NECK DISSECTION SUBMENTAL FLAP NERVE RESECTION AND NERVE GRAFT'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '1000'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'three times daily (TID)'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '12 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:53:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:29:38

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B, PRODUCTSYNONYM: SENNA AND DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:51:30
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 19:51:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:12
Data point term sent to Coder	System	16 Apr 2021 11:32:17
Data point term sent to Coder	System	16 Apr 2021 11:31:14
User entered 'docusate sodium; comb; senna concentrate'	Angela Snyder (b) (4) (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'constipation prevention'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '8.6/50'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'mg (mg)'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 11:31:54
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Angela Snyder (b) (4)	16 Apr 2021 11:31:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Apr 2021 11:31:08
	Angela Snyder (b) (4)	16 Apr 2021 11:31:08
	(b) (4)	

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '12 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered '0'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:52:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:23:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:31:08

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:23:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	04 Mar 2021 19:39:48
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	17 Sep 2020 14:22:21

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:23:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
Signature has been broken.	(b) (4)	
	MaKayla Bishop (b) (4)	24 Mar 2021 19:02:39
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
	(b) (4)	
User entered '14 Jan 2021'	Angela Snyder (b) (4)	15 Mar 2021 15:29:27
	(b) (4)	

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'ct lung screening'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:29:27

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Other (OTHER)'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:29:27

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'screening, history of smoking'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:29:27

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '11 Feb 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:29:49

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'echo stress test'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:29:49

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
Signature has been broken.	(b) (4) MaKayla Bishop (b) (4)	24 Mar 2021 19:03:15
User entered 'Medical History (MH)' reason for change: Data Entry Error	(b) (4) MaKayla Bishop (b) (4)	24 Mar 2021 19:03:15
User signature succeeded.	(b) (4) Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Adverse Event (AE)'	(b) (4) Angela Snyder (b) (4)	15 Mar 2021 15:29:49
	(b) (4)	

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:54:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:29:49

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '25 Feb 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:11

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'ct neck with contrast'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:11

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Adverse Event (AE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:11

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:11

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:23:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '5 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:37

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'fna needle biopsy'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:37

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Adverse Event (AE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:37

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:20
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:30:37

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:16
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered '11 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:31:09

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:16
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'nm det ct skull thigh'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:31:09

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:16
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered 'Adverse Event (AE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:31:09

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:16
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:06:36
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	15 Mar 2021 15:31:09

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:52:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '16 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:32:34

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:52:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'incisional biopsy of neck mass'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:32:34

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:52:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Adverse Event (AE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:32:34

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:52:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:32:34

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '11 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:18

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mri orbit face neck w/without contrast'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:18

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Adverse Event (AE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:18

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:18

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered '11 Mar 2021'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:52

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'mri head w/without contrast'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:52

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered 'Adverse Event (AE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:52

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:23:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:53:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:25
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:33:52

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:55:08
User entered '08 Apr 2021'	MaKayla Bishop (b) (4)	09 Apr 2021 19:35:37
	(b) (4)	

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:23:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:55:08
User entered 'Leftparotidectomy left neck dissection submental flap nerve resection and nerve graft.'	MaKayla Bishop (b) (4)	09 Apr 2021 19:35:37
	(b) (4)	

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:23:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:55:08
User entered 'Adverse Event (AE)'	MaKayla Bishop (b) (4)	09 Apr 2021 19:35:37
	(b) (4)	

US3662101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:23:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:55:08
User entered empty.	MaKayla Bishop (b) (4)	09 Apr 2021 19:35:37
	(b) (4)	

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered		
'USA-US088-2021-MRNA-1273-P301000010'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Carl'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Fichtenbaum'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered '231 Albert Sabin Way'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Cincinnati'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered '45267'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:34:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
User entered 'US'	System	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:35:07
User entered '1'	System	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'USA-US088-2021-MRNA-1273-P301000010'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Carl'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Fichtenbaum'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered '231 Albert Sabin Way'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Cincinnati'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered '45267'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:34:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
User entered 'US'	System	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:35:07
User entered '1'	System	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:23:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
User entered '12/Apr/2021 06:08'	System	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:23:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:34:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'USA-US088-2021-MRNA-1273-P301000010'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'No (N)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Yes (Y)'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Carl'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Fichtenbaum'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered '231 Albert Sabin Way'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered 'Cincinnati'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 15:42:31
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:20
User entered '45267'	System	12 Apr 2021 13:07:53

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:34:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:42:31
User entered 'US'	System	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:23:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:35:07
User entered '1'	System	12 Apr 2021 13:08:27

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:23:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:41:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:56:27
User entered '19/Apr/2021 15:35'	System	19 Apr 2021 20:35:07

US3662101

Folder: SAE USA-US088-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:23:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:41:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:56:27
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 20:35:07