

US3522666 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:03:14

All time stamps listed in this document are displayed in GMT

US3522666

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 19:22:03

Generated On: 10 Jun 2021 08:03:14

[Participant ID](#)

US3522666

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

US3522666

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:22:05

Generated On: 10 Jun 2021 08:03:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 19:22:05

Generated On: 10 Jun 2021 08:03:14

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:22:05

Generated On: 10 Jun 2021 08:03:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:15 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:15
Height (<i>xxx.x</i>)	70.1 in
Weight (<i>xxx.x</i>)	295.4 lb
BMI (<i>xxx.x</i>)	42.35302 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:22:05

Generated On: 10 Jun 2021 08:03:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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) 05 Mar 2021 19:22:05

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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

SALES AND MARKETING

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:22:05

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 190557

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) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

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) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	13:52 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:52
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

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) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 13:44 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:44

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) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

13:00 (24 HR)

Collection date and time (derived)

11 SEP 2020 13:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:07	11 SEP 2020 13:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

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 08:03:14

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 14:04

PC Close Date & Time

11 SEP 2020 16:34

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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 97.5 °F

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

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

PC Time Stamp	11 SEP 2020 20:02
PC Open Date & Time	11 SEP 2020 17:29
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 14:03

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	13 SEP 2020 12:08
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 15:19

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 19:43

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

16 SEP 2020 19:53

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 23:41

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

11 SEP 2020 14:04

PC Close Date & Time

11 SEP 2020 16:34

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

11 SEP 2020 20:03

PC Open Date & Time

11 SEP 2020 17:29

PC Close Date & Time

12 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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)

2

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

12 SEP 2020 14:04

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

13 SEP 2020 12:08

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

14 SEP 2020 15:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

15 SEP 2020 19:44

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

16 SEP 2020 19:53

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

17 SEP 2020 23:41

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 14:04

PC Close Date & Time

11 SEP 2020 16:34

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:03
PC Open Date & Time	11 SEP 2020 17:29
PC Close Date & Time	12 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

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)

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US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 14:05
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:09
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3747

EAB) (1725)

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 15:20
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 3747

EAB) (1725)

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:44
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

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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US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:54
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

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 ☒

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 23:42
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 SEP 2020 22:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

20 SEP 2020 16:44

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

22 SEP 2020 11:07

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 SEP 2020 22:14

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 SEP 2020 16:44

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 SEP 2020 22:14

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 SEP 2020 16:44

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 SEP 2020 11:07

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 22:14
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 16:44
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522666

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PT REPORTS PAIN/SORENESS
AROUND INJECTION SITE AND
NAUSEA 36-48 HOURS AFTER
RECEIVING FIRST INJECTION
ON 11SEP2020, AND SYMPTOMS
RESOLVED 17SEP2020. DOES
NOT WISH TO SPEAK STUDY
DOCTOR

US3522666

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments PATIENT REPORTING ONLY
CONTINUING AE SOME JOINT
PAIN IN SHOULDER, TAKEN
MOTRIN, NO NEW ILLNESS OR
HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

If Contact Not Made, please provide Comments

US3522666

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

"NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK."

US3522666

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:35
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 10:32
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3522666

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

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) 12 OCT 2020

What was the treatment time? (00:00-23:59) 10:02 (24 HR)

Treatment Date and Time (derived) 12 OCT 2020 10:02

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

US3522666

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

09:53 (24 HR)

Collection date and time (derived)

12 OCT 2020 09:53

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Collection date (dd MMM yyyy)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:55	12 OCT 2020 09:55
Nasopharyngeal Swab 2	No		

US3522666

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 OCT 2020 10:22

PC Close Date & Time

12 OCT 2020 12:52

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	13 OCT 2020 06:04
PC Open Date & Time	12 OCT 2020 13:47
PC Close Date & Time	13 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 11:47

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 02:06

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

19 OCT 2020 09:47

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

12 OCT 2020 10:22

PC Close Date & Time

12 OCT 2020 12:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

5

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☒

No ☐

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

1

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

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

13 OCT 2020 06:06

PC Open Date & Time

12 OCT 2020 13:47

PC Close Date & Time

13 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

15 OCT 2020 11:47

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

17 OCT 2020 02:07

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

19 OCT 2020 09:48

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 10:27
PC Open Date & Time	12 OCT 2020 10:22
PC Close Date & Time	12 OCT 2020 12:52

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 06:07
PC Open Date & Time	12 OCT 2020 13:47
PC Close Date & Time	13 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

Yes ☐

PC Time stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

118 of 3747

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 11:48
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

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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US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

Yes ☐

PC Time stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 02:07
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

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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US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

Yes ☐

PC Time stamp

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

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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US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 09:48
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3522666

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

SEE SOURCE. NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE.

If Contact Not Made, please provide Comments

US3522666

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

"NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK."

US3522666

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:28:29

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522666

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 NOV 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	09 NOV 2020 11:00
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522666

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 NOV 2020

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

US3522666

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 NOV 2020

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

9 NOV 2020 11:10

US3522666

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:50

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

13 NOV 2020 16:42:42

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 DEC 2020 15:17:11
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 12:48:11
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 11:29:01
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

23 DEC 2020 18:01:53

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:01:57

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 22:48:46
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 17:59:56
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 13:56:13
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 JAN 2021 00:16:09
Patient Cloud Open Date & Time	24 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
162 of 3747	

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

04 FEB 2021 11:59:53

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	09 FEB 2021 10:07:34
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 09:50:28

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:01:39

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 16:22:33
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 MAR 2021 01:31:15
Patient Cloud Open Date & Time	21 MAR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
173 of 3747	

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 APR 2021 13:23:02
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 APR 2021 17:58:30
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

15 APR 2021 15:15:35

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

22 APR 2021 23:05:58

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

Patient Cloud Open Date & Time	25 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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°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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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°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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3522666

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:03:14

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		11 MAR 2021 16:22:45

US3522666

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

SEE SOURCE

If Contact Not Made, please provide Comments

US3522666

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT VM

If Contact Not Made, please provide Comments

US3522666

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 20:47:51

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PER PHONE CALL 10FEB2021,
SUBJECT REPORTED COVID
RELATED SYMPTOMS THAT
STARTED 06FEB2021, LASTED
FOR AT LEAST 48HOURS.

US3522666

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 15:32:06

Generated On: 10 Jun 2021 08:03:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 MAR 2021

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

Comments
If Contact Not Made, please provide Comments

CHEMICAL CARDIAC STRESS
TEST A MONTH AGO WHICH
WAS ABNORMAL SO
SCHEDULED FOR CARDIAC
CATHERIZATION ON 12 MAR
2021. OTHERWISE, NO AES
REPORTED, NO OTHER
CHANGES IN HEALTH STATUS,
NO COVID-19 EXPOSURE.

US3522666

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 15:32:06

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522666

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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 _____

US3522666

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	

US3522666

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

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.

US3522666

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<input type="text"/>
Collection time (<i>00:00-23:59</i>)	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

US3522666

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522666

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:03:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522666

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

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

Visit date (dd MMM yyyy)	18 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3522666

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 15:32:06

Generated On: 10 Jun 2021 08:03:14

Date of updated informed consent (dd MMM yyyy) 18 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) 18 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 _____

US3522666

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

12:32 (24 HR)

Collection date and time (derived)

18 JAN 2021 12:32

US3522666

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 19:22:04

Generated On: 10 Jun 2021 08:03:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	12:35
Collection Date and Time (derived)	18 JAN 2021 12:35

US3522666

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 19:22:03

Generated On: 10 Jun 2021 08:03:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	HALLUCINATION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 OCT 2020
Start time (00:00-23:59)	03:00 (24 HR)
AE start date and time (derived)	13 OCT 2020 03:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 OCT 2020
End time (00:00-23:59)	04:00 (24 HR)
AE End Date and Time (derived)	13 OCT 2020 04:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

AEID

Adverse event

NAUSEA REMAINING AFTER 7
DAYS AFTER 2ND INJECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT STARTED EXPERIENCING FATIGUE 06-FEB-2021 WHICH IS ONGOING AS OF 10-FEB-2021 BUT STARTING TO RESOLVE.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT STATES NAUSEA STARTED 07-FEB-2021 AND RESOLVED 08-FEB-2021. SEE SOURCE NOTE FOR DETAILS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT DEVELOPED DIARRHEA ON 08-FEB-2021 FOR WHICH HE TOOK PEPTO BISMOL "2 TABLESPOONS" 3 TIMES THROUGHOUT THE DAY. HE STATES THAT BY 09-FEB-2021 MID MORNING, THE DIARRHEA HAD RESOLVED.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	BODY ACHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	BODY ACHES STARTED 08-FEB-2021 AND RESOLVED 10-FEB-2021. SEE SOURCE NOTE FOR DETAILS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

AEID

Adverse event

POSITIVE CARDIAC STRESS
TEST

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 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)

8 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	WORSENING OF CORONARY ARTERY DISEASE
Narrative	HAD CHEMICAL CARDIAC STRESS TEST A MONTH AGO WHICH WAS ABNORMAL SO IS SCHEDULED FOR CARDIAC CATHERIZATION ON 12 MAR 2021
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 (9)

Generated On: 10 Jun 2021 08:03:14

AEID	USA-US131-2021-MRNA-1273-P30 1000013
Adverse event	WORSENING OF CORONARY ARTERY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	26 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	1
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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

UNDERWENT EVALUATION
FOR SYMPTOMS OF
EXERTIONAL ANGINA
(POSITIVE STRESS STRESS
08-FEB-2021). CARDIAC
CATHERIZATION 12-MAR-2021
DEMONSTRATED
MULTI-VESSEL CORONARY
ARTERY DISEASE AND
UNDERWENT THE GRAFTING
FOR THAT
ON 16 MAR 2021...23 MAR 2021
CALL (DOCUMENTED
SYMPTOMS OF SOB,
DIFFICULTY BREATHING,
FATIGUE, BODY ACHES,
HEADACHE AND NAUSEA IN
E-DIARY), HE SAYS HE'S DOING
BETTER AND POSSIBLY WILL
BE PLACED IN OUTPATIENT
REHAB ON 24 MAR 2021 WHERE
HE WILL STAY 4-5 DAYS

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

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	POST CABG PLEURAL EFFUSION, THORACENTESIS PERFORMED ON 22 MAR 2021 (730 CC REMOVED). 24 MAR 2021 CHEST X-RAY SHOWS INTERVAL DECREASE IN LEFT EFFUSION
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	MYALGIA- MILD
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	ARTHRALGIA-MILD
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

AEID	
Adverse event	ELECTROLYTE DISTURBANCE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (14)

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Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT FOUND TO HAVE LOW THEN HIGH POTASSIUM LEVELS, WAS TREATED WITH ELECTROLYTES TO BALANCE.
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) 05 Mar 2021 19:22:03

Generated On: 10 Jun 2021 08:03:14

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)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	ELIQUIS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	A FIB
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	LIPITOR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Start date completely unknown		True
<hr/>		
Ongoing?		Yes <input type="checkbox"/>
		No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		6 APR 2021
<hr/>		
Was this medication taken for solicited event?		Yes <input type="checkbox"/>
		No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		1
<hr/>		
Interval Dosage Unit Number (derived)		1
<hr/>		
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input checked="" type="checkbox"/>
<hr/>		

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	LEXAPRO
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	PROSCAR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BPH
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	FLOMAX
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BPH
Dose per administration	0.4
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	MOTRIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PAIN AT SITE OF INJECTION
Dose per administration	200
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	LISINOPRIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HEADACHE, BODY ACHES
Dose per administration	650
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (<i>dd MMM yyyy</i>)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		13 OCT 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CARDIO PROTECTIVE
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	PEPTO BISMOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIARRHEA
Dose per administration	525
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		8 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	LIPITOR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	FUROSEMIDE (LASIX)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PLEURAL EFFUSION
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	19 MAR 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 MAR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SURGERY PAIN
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SURGERY PAIN
Dose per administration	650
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	ALBUMIN HUMAN 5 % INFUSION
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	POST SURGICAL
Dose per administration	12.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	17 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	ALLOPURINOL (ZYLOPRIM)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	UNKNOWN WHY RECEIVED TWO DOSES
Dose per administration	300
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	CALCIUM GLUCONATE 1 G IN DEXTROSE 5 % 50 ML INFUSION 1 G, ADMINISTER OVER 30 MINUTES, INTRAVENOUS, ONCE,
--------------------	---

Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
-------------	--

Indication	ELECTROLYTE REPLACEMENT
------------	-------------------------

Dose per administration	1
-------------------------	---

Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
-----------	--

If dose unit is Other, specify

Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify

Route of administration	Oral <input type="radio"/> Topical <input type="radio"/>
-------------------------	---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	17 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
<hr/>		
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	CEFTRIAXONE (ROCEPHIN)
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SURGICAL INFECTIONS PROPHYLAXIS
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	COLACE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CONSTIPATION PROPHYLAXIS
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	EPINEPHRINE (ADRENALIN)1 MG IN DEXTROSE 5 % 250 ML INFUSION
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CORONARY ARTERY DISEASE
Dose per administration	0.1-10
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	0.1-10 MCG/MIN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	PEPCID
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PREVENTS ULCERS
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
If route of administration is Other, specify	BOTH IV AND ORAL	
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	HEPARIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	BLOOD CLOTS PROPHYLAXIS/CORONARY ARTERY DISEASE
Dose per administration	400-3000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	CONTINUOUS Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	HEPARIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	BLOOD CLOTS PROPHYLAXIS
Dose per administration	5000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

Name of Medication HYDROCODONE-ACETAMINOP
HEN (NORCO)

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL PAIN

Dose per administration 5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 22 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	HYDROMORPHONE (DILAUDID)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POST SURGICAL PAIN
Dose per administration	0.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	INSULIN GLARGINE (LANTUS)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES
Dose per administration	18
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES TYPE 2
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	INSULIN GLARGINE (LANTUS)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES
Dose per administration	25
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	INSULIN GLARGINE (LANTUS)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIABETES
Dose per administration	32
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input checked="" type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input checked="" type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		13 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		15 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	INSULIN GLARGINE (LANTUS)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIABETES
Dose per administration	32
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input checked="" type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	DAILY AT HOUR OF SLEEP Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input checked="" type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

Name of Medication INSULIN LISPRO (HUMALOG)
INJECTION

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 2-5

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

If dose unit is Other, specify

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

If frequency is Other, specify

BEFORE MEALS AND AT
BEDTIME

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		13 MAR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

Name of Medication INSULIN LISPRO (HUMALOG)

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 2-5

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

If dose unit is Other, specify

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

If frequency is Other, specify

BEFORE MEALS AND AT
BEDTIME

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)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	INSULIN LISPRO (HUMALOG)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIABETES
Dose per administration	4
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input checked="" type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	WITH LUNCH Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input checked="" type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)		24 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	INSULIN LISPRO (HUMALOG)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES
Dose per administration	4
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	WITH DINNER Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

Name of Medication INSULIN LISPRO (HUMALOG)
INJECTION

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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

THREE TIMES DAILY WITH
MEALS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	INSULIN REGULAR HUMAN HUMULIN R
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES
Dose per administration	10
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	LIDODERM PATCH 5%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POST SURGICAL PAIN
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	PATCH
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input checked="" type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	LIDOCAINE (XYLOCAINE) 1 %
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	IV START PAIN
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
If route of administration is Other, specify	INTRADERMAL	
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	LISINOPRIL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	MAGNESIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ELECTROLYTE DISTURBANCE
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	MAGNESIUM OXIDE (MAG-OXIDE)
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	VITAMIN
Dose per administration	400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	MAGNESIUM SULFATE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ELECTROLYTE DISTURBANCE
Dose per administration	2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input checked="" type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

Name of Medication MELATONIN TABLET 6 MG
6 MG, ORAL, EVERY NIGHT AT
BEDTIME

Prophylaxis Yes ☒
No ☐

Indication SLEEP IN HOSPITAL

Dose per administration 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

EVERY NIGHT AT BEDTIME

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	METOPROLOL (LOPRESSOR)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	12.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

Name of Medication METOPROLOL (LOPRESSOR)
TABLET 12.5 MG
12.5 MG, ORAL, EVERY 12
HOURS 3/25/21-3/26/21

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

Name of Medication METOPROLOL (LOPRESSOR)
TABLET 25 MG
, ORAL, EVERY 12 HOURS
3/19/21 FOR HYPERTENSION

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	MUPIROCIN (BACTROBAN) 2 %
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PRE AND POST OP PROPHYLAXIS FOR INFECTION
Dose per administration	0.25
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	8 DOSES Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		17 MAR 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

Name of Medication NITROGLYCERIN 50 MG IN
DEXTROSE 5 % 250 ML
INFUSION

Prophylaxis Yes ☐
No ☒

Indication WORSENING CORONARY
ARTERY DISEASE

Dose per administration 5-200

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

If dose unit is Other, specify

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		14 MAR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	NOREPINEPHRINE (LEVOPHED)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	WORSENING CORONARY ARTERY DISEASE
Dose per administration	0.5-12
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	CONTINUOUS Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		17 MAR 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

Name of Medication POLYETHYLENE GLYCOL 3350
(MIRALAX)

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 17

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 (51)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		20 MAR 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	POTASSIUM CHLORIDE (KLOR-CON) CR TABLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ELECTROLYTE DISTURBANCE
Dose per administration	40
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MEQ
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	FOUR DOSES
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	POTASSIUM CHLORIDE INTERMITTENT INFUSION
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ELECTROLYTE DISTURBANCE
Dose per administration	20
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MEQ
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	EVERY TWO HOURS FOR 3 DOSES
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	PROPOFOL (DIPRIVAN)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PROCEDURAL SEDATION
Dose per administration	4.3-85.2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	ML PER HOUR
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	CONTINUOUS
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	SENNA
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CONSTIPATION PROPHYLAXIS
Dose per administration	17.2
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

Name of Medication POTASSIUM PHOSPHATE
(K-PHOS ORIGINAL)

Prophylaxis Yes ☐
No ☒

Indication ELECTROLYTE DISTURBANCE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	SODIUM BICARBONATE 8.4 % INJECTION
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ELECTROLYTE DISTURBANCE
Dose per administration	25
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MEQ
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

Name of Medication SULFAMETHOXAZOLE-TRIMET
HOPRIM DOUBLE STR
(BACTRIM DS)

Prophylaxis Yes ☐
No ☒

Indication PROPHYLACTIC TREATMENT
OF POSSIBLE UTI (CULTURE
NEGATIVE)

Dose per administration 800-160

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

Name of Medication	TRAMADOL
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	POST SURGICAL PAIN
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 15:32:06

Generated On: 10 Jun 2021 08:03:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 14 Apr 2021 22:35:35

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 FEB 2021	CHEMICAL CARDIAC STRESS TEST	Medical History	
16 MAR 2021	CORONARY ARTERY BYPASS GRAFTING X3 (LIMA TO LAD, SVG TO OM, SVG TO PDA)	Medical History	
16 MAR 2021	ENDOSCOPIC VEIN HARVESTING OF THE LEFT GREATER SAPHENOUS VEIN	Medical History	
16 MAR 2021	EXCISION OF LEFT ATRIAL APPENDAGE	Medical History	
16 MAR 2021	OPEN REDUCTION RIGID INTERNAL STERNAL FIXATION (STERNALOCK PLANTING SYSTEM)	Medical History	
22 MAR 2021	THORACENTESIS (LEFT PLEURAL EFFUSION)	Adverse Event	
12 MAR 2021	CORONARY ANGIOGRAPHY	Adverse Event	

US3522666

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:03:14

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

US3522666

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:03:14

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 ☐

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/MAR/2021 16:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522666

Folder: SAE-USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/MAR/2021 10:28
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

US3522666

Folder: SAE-USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/MAR/2021 08:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/APR/2021 14:21
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

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/APR/2021 11:19
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

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	27/APR/2021 10:59
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

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 17:47:24

Generated On: 10 Jun 2021 08:03:14

SAEID	USA-US131-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/APR/2021 18:40
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

US3522666 (Prod: Henry Ford Health System)

US3522666

Form: Participant Creation

Generated On: 10 Jun 2021 08:03:14

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 00:02:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered 'US3522666'	RWS_ENDPOINT	11 Sep 2020 16:19:29
	ENDPOINT (b) (4)	
	(b) (4)	

US3522666

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:21:29

US3522666

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:13
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:19:30

US3522666

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 16:21:29

US3522666

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'SCRN'	System	11 Sep 2020 16:21:29

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:19:31

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '76'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'YEARS'	System	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered '76'	System	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered 'Male (M)'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:17
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:21:47

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'Sep 2020'	System	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered '2020'	System	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:23

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:19:30

US3522666

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'I'	System	11 Sep 2020 16:39:47

US3522666

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:03:14

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:39:47

US3522666

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:03:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:03:23

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:43
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:52:21
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Eliquis indication added' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:36:12
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:52:16
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: AFib - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:13:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:13:45
Data point term sent to Coder	System	11 Sep 2020 17:13:07
User entered 'Afib'	(b) (4), (b) (6)	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:43
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:43
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:43
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:43
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:12:21

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:46
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 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) (b) (4)	11 Sep 2020 17:13:48
Data point term sent to Coder	System	11 Sep 2020 17:13:10
User entered 'anxiety'	(b) (4), (b) (6)	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:46
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:46
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:10:46
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:10:46
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:10

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Please spell out CAD.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Feb 2021 06:51:41
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.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 20:28:41
Data point term sent to Coder	System	04 Feb 2021 20:27:18
Query 'Please spell out CAD.' answered with 'UPDATED' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	04 Feb 2021 20:26:38
Coding entries removed.	Alayna Wilder (b) (4) (b) (4)	04 Feb 2021 20:26:19
User entered 'CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	04 Feb 2021 20:26:19
User opened query 'Please spell out CAD.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 20:11:07
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.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:14:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:14:45
Data point term sent to Coder	System	11 Sep 2020 17:14:11
User entered 'CAD'	(b) (4), (b) (6)	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:25

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:16
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:14:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:14:46
Data point term sent to Coder	System	11 Sep 2020 17:14:15
User entered 'Depression'	(b) (4), (b) (6)	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:16
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:16
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:16
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:16
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:41

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:18
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 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:14:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:14:46
Data point term sent to Coder	System	11 Sep 2020 17:14:15
User entered 'diabetes type 2'	(b) (4), (b) (6)	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:18
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:18
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:18
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:13:58

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:22
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:53:21
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'fixed' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:05:36
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:53:01
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:15:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:15:40
Data point term sent to Coder	System	11 Sep 2020 17:14:20
User entered 'hypertension'	(b) (4), (b) (6)	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:22
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:22
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:16

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:27
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.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:15:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:15:42
Data point term sent to Coder	System	11 Sep 2020 17:15:20
User entered 'hyperlipidemia'	(b) (4), (b) (6)	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:27
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:27
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:27
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:27
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	11 Sep 2020 17:14:32

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:51:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:51:34
Data point term sent to Coder	System	16 Oct 2020 15:50:22
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:49:59
User entered 'Benign Prostatic Hyperplasia' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	16 Oct 2020 15:49:59
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:33:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:33:39
Data point term sent to Coder	System	24 Sep 2020 18:32:19
User entered 'BPH'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:41
User entered empty.	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:41
User entered 'I'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:41
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:41
User entered empty.	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:41
User entered '0'	Kristin Eis (b) (4)	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered empty.	System	24 Sep 2020 18:31:41

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered '12:15'	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered '11 Sep 2020 12:15'	System	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered '70.1' in	(b) (4), (b) (6)	11 Sep 2020 17:04:04
DataPoint set to visible.	System	11 Sep 2020 16:39:47

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered '295.4' lb	(b) (4), (b) (6)	11 Sep 2020 17:04:04
DataPoint set to visible.	System	11 Sep 2020 16:39:47

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered '42.35302'	System	11 Sep 2020 17:04:04
DataPoint set to visible.	System	11 Sep 2020 16:39:47

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'kg/m2'	System	11 Sep 2020 17:04:04
DataPoint set to visible.	System	11 Sep 2020 16:39:47

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'bpm'	System	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'breaths/min'	System	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'mmHg'	System	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User entered 'mmHg'	System	11 Sep 2020 17:04:04

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47

US3522666

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47

US3522666

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:11:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:04:14

US3522666

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:11:59
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:04:14

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:05:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:05:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:09
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:04:50
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered 'Sales and marketing'	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

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 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:39:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:02
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:04:50

US3522666

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:05:21

US3522666

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:09
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:05:21

US3522666

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 17:05:21

US3522666

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'VISIT1'	System	11 Sep 2020 17:05:21

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:24:38

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered '190557'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:24:38

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:24:38

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

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)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:05:36

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

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)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:05:36

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:05:36

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:05:36

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:05:36

US3522666

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:14

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:13
User entered 'No (N)'	Kristin Eis (b) (4)	24 Sep 2020 18:32:22
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 06:11:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:11:35

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '12:15'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered '11 Sep 2020 12:15'	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '98.1' F	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	15 Sep 2020 15:18:41
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	11 Sep 2020 17:06:16
User entered 'Other (Other)'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered 'Temporal' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:18:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '51'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'bpm'	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'breaths/min'	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '122'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'mmHg'	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '71'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'mmHg'	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4) (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 15:20:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 15:20:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	15 Sep 2020 15:20:06
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:06:16
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '11 Sep 2020' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User closed query 'Per CDM: The treatment time on the Exposure CRF is 13:44 and the Vital Signs Post Dose Time of Assessment is 13:52 which has 8 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM). Query 'Per CDM: The treatment time on the Exposure CRF is 13:44 and the Vital Signs Post Dose Time of Assessment is 13:52 which has 8 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' answered with 'participant had to leave prior to 30 min wait time due to having an appointment ' (Site from DM).	(b) (4), (b) (6) Jelena Verkler (b) (4) (b) (4)	23 Oct 2020 11:30:52 20 Oct 2020 13:46:22
User opened query 'Per CDM: The treatment time on the Exposure CRF is 13:44 and the Vital Signs Post Dose Time of Assessment is 13:52 which has 8 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 04:21:25
User entered '13:52' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered '11 Sep 2020 13:52'	System	15 Sep 2020 15:20:06
User entered empty.	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '97.5' F reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered 'Other (Other)' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered 'Temporal' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '64' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'bpm'	System	15 Sep 2020 15:20:06
User entered empty.	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '16' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'breaths/min'	System	15 Sep 2020 15:20:06
User entered empty.	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '123' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'mmHg'	System	15 Sep 2020 15:20:06
User entered empty.	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:16
User entered '65' reason for change: Data Entry Error	Jelena Verkler (b) (4)	15 Sep 2020 15:20:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'mmHg'	System	15 Sep 2020 15:20:06
User entered empty.	System	11 Sep 2020 17:06:16

US3522666

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:06:22

US3522666

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:27
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:06:22

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:23
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:25:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

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)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:23
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:23
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:23
User entered '13:44'	(b) (4), (b) (6)	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered '11 Sep 2020 13:44'	System	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:23
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:12:23
User entered 'ONCE'	System	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 18:25:29

US3522666

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:25:47

US3522666

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:31
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:25:47

US3522666

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:31
User entered '13:00'	(b) (4), (b) (6)	11 Sep 2020 18:25:47

US3522666

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered '11 Sep 2020 13:00'	System	11 Sep 2020 18:25:47

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:03:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:36
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:36
User entered '13:07'	(b) (4), (b) (6)	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered '11 Sep 2020 13:07'	System	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:36
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:36
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered empty.	System	11 Sep 2020 18:26:02

US3522666

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:26:07

US3522666

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'I'	System	11 Sep 2020 18:26:07

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 14:04'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 16:34'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:02:35', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '39d1beae-0e33-46a8-84ec-0274cdbb75ad' User entered 'Yes (Y)'	System	12 Sep 2020 00:02:53
	System	12 Sep 2020 00:02:53

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:02:41', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '39d1beae-0e33-46a8-84ec-0274cdbb75ad' User entered '97.5'	System	12 Sep 2020 00:02:53
	System	12 Sep 2020 00:02:53

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:02:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '39d1beae-0e33-46a8-84ec-0274cdbb75ad'	System	12 Sep 2020 00:02:53
User entered 'No (N)'	System	12 Sep 2020 00:02:53

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:02:51', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '39d1beae-0e33-46a8-84ec-0274cdbb75ad' User entered '11 Sep 2020 20:02'	System	12 Sep 2020 00:02:53
	System	12 Sep 2020 00:02:53

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 17:29'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 2'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:02:52', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'e65384c2-f87c-407a-a7c6-d5c59451bf23' User entered 'Yes (Y)'	System	12 Sep 2020 18:03:16
	System	12 Sep 2020 18:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:03:01', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'e65384c2-f87c-407a-a7c6-d5c59451bf23' User entered '98.2'	System	12 Sep 2020 18:03:16
	System	12 Sep 2020 18:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:03:08', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'e65384c2-f87c-407a-a7c6-d5c59451bf23'	System	12 Sep 2020 18:03:16
User entered 'No (N)'	System	12 Sep 2020 18:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:03:15', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'e65384c2-f87c-407a-a7c6-d5c59451bf23' User entered '12 Sep 2020 14:03'	System	12 Sep 2020 18:03:16
	System	12 Sep 2020 18:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 3'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:07:31', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '33ffea90-b23a-469f-96ba-301eded2b219' User entered 'Yes (Y)'	System	13 Sep 2020 16:08:09
	System	13 Sep 2020 16:08:09

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:07:47', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '33ffea90-b23a-469f-96ba-301eded2b219' User entered '97.8'	System	13 Sep 2020 16:08:09
	System	13 Sep 2020 16:08:09

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:07:53', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '33ffea90-b23a-469f-96ba-301eded2b219'	System	13 Sep 2020 16:08:09
User entered 'Yes (Y)'	System	13 Sep 2020 16:08:09

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
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 'Motrin added' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 09:02:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:03', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '33ffea90-b23a-469f-96ba-301eded2b219'	System	13 Sep 2020 16:08:09
User entered '1'	System	13 Sep 2020 16:08:09

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:03', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '33ffea90-b23a-469f-96ba-301eded2b219' User entered '0'	System	13 Sep 2020 16:08:09
	System	13 Sep 2020 16:08:09

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:06', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '33ffea90-b23a-469f-96ba-301eded2b219'	System	13 Sep 2020 16:08:09
User entered '13 Sep 2020 12:08'	System	13 Sep 2020 16:08:09

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 4'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:19:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a111c710-1620-4527-a458-016c6c78895b' User entered 'Yes (Y)'	System	14 Sep 2020 19:19:33
	System	14 Sep 2020 19:19:33

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:19:22', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a111c710-1620-4527-a458-016c6c78895b' User entered '98.2'	System	14 Sep 2020 19:19:33
	System	14 Sep 2020 19:19:33

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:19:26', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a111c710-1620-4527-a458-016c6c78895b' User entered 'No (N)'	System	14 Sep 2020 19:19:33
	System	14 Sep 2020 19:19:33

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:19:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a111c710-1620-4527-a458-016c6c78895b' User entered '14 Sep 2020 15:19'	System	14 Sep 2020 19:19:33
	System	14 Sep 2020 19:19:33

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 5'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:43:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5cbfe197-2ee6-4479-911f-bf70b6c6a19e' User entered 'Yes (Y)'	System	15 Sep 2020 23:43:43
	System	15 Sep 2020 23:43:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:43:32', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5cbfe197-2ee6-4479-911f-bf70b6c6a19e' User entered '98.5'	System	15 Sep 2020 23:43:43
	System	15 Sep 2020 23:43:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:43:36', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5cbfe197-2ee6-4479-911f-bf70b6c6a19e' User entered 'No (N)'	System	15 Sep 2020 23:43:43
	System	15 Sep 2020 23:43:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:43:39', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5cbfe197-2ee6-4479-911f-bf70b6c6a19e' User entered '15 Sep 2020 19:43'	System	15 Sep 2020 23:43:43
	System	15 Sep 2020 23:43:43

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 6'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c8a33b3c-36eb-46af-934f-86fca7353011' User entered 'Yes (Y)'	System	16 Sep 2020 23:53:27
	System	16 Sep 2020 23:53:27

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:19', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c8a33b3c-36eb-46af-934f-86fca7353011' User entered '98.3'	System	16 Sep 2020 23:53:27
	System	16 Sep 2020 23:53:27

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:22', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c8a33b3c-36eb-46af-934f-86fca7353011' User entered 'No (N)'	System	16 Sep 2020 23:53:27
	System	16 Sep 2020 23:53:27

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:25', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c8a33b3c-36eb-46af-934f-86fca7353011' User entered '16 Sep 2020 19:53'	System	16 Sep 2020 23:53:27
	System	16 Sep 2020 23:53:27

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 7'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a81f823b-331a-4ca8-b47a-0ebaf0eb73fe' User entered 'Yes (Y)'	System	18 Sep 2020 03:41:17
	System	18 Sep 2020 03:41:17

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:07', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a81f823b-331a-4ca8-b47a-0ebaf0eb73fe' User entered '98.2'	System	18 Sep 2020 03:41:17
	System	18 Sep 2020 03:41:17

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:11', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a81f823b-331a-4ca8-b47a-0ebaf0eb73fe' User entered 'No (N)'	System	18 Sep 2020 03:41:17
	System	18 Sep 2020 03:41:17

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a81f823b-331a-4ca8-b47a-0ebaf0eb73fe' User entered '17 Sep 2020 23:41'	System	18 Sep 2020 03:41:17
	System	18 Sep 2020 03:41:17

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 14:04'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 16:34'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:02:57', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '8c9a2c3e-b19b-4ea6-9f2a-683697c4957e' User entered 'None (1)'	System	12 Sep 2020 00:03:16
	System	12 Sep 2020 00:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:01', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '8c9a2c3e-b19b-4ea6-9f2a-683697c4957e' User entered 'No (N)'	System	12 Sep 2020 00:03:16
	System	12 Sep 2020 00:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:04', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '8c9a2c3e-b19b-4ea6-9f2a-683697c4957e' User entered 'No (N)'	System	12 Sep 2020 00:03:16
	System	12 Sep 2020 00:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:08', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '8c9a2c3e-b19b-4ea6-9f2a-683697c4957e' User entered 'None (1)'	System	12 Sep 2020 00:03:16
	System	12 Sep 2020 00:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:13', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '8c9a2c3e-b19b-4ea6-9f2a-683697c4957e' User entered '11 Sep 2020 20:03'	System	12 Sep 2020 00:03:16
	System	12 Sep 2020 00:03:16

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 17:29'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 2'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:03:49', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '9156d51c-2568-41b2-aa54-e727da7324a8'	System	12 Sep 2020 18:04:58
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	12 Sep 2020 18:04:58

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:04:03', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '9156d51c-2568-41b2-aa54-e727da7324a8' User entered 'No (N)'	System	12 Sep 2020 18:04:58
	System	12 Sep 2020 18:04:58

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:04:08', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '9156d51c-2568-41b2-aa54-e727da7324a8' User entered 'Yes (Y)'	System	12 Sep 2020 18:04:58
	System	12 Sep 2020 18:04:58

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:04:34', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '9156d51c-2568-41b2-aa54-e727da7324a8' User entered '2'	System	12 Sep 2020 18:04:58
	System	12 Sep 2020 18:04:58

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:04:51', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '9156d51c-2568-41b2-aa54-e727da7324a8'	System	12 Sep 2020 18:04:58
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 18:04:58

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:04:54', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '9156d51c-2568-41b2-aa54-e727da7324a8' User entered '12 Sep 2020 14:04'	System	12 Sep 2020 18:04:58
	System	12 Sep 2020 18:04:58

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 3'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'bdef565e-6e43-4673-9c6f-3b32eae11279'	System	13 Sep 2020 16:08:48
User entered 'None (1)'	System	13 Sep 2020 16:08:48

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:18', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'bdef565e-6e43-4673-9c6f-3b32eae11279' User entered 'No (N)'	System	13 Sep 2020 16:08:48
	System	13 Sep 2020 16:08:48

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:22', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'bdef565e-6e43-4673-9c6f-3b32eae11279' User entered 'No (N)'	System	13 Sep 2020 16:08:48
	System	13 Sep 2020 16:08:48

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:41', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'bdef565e-6e43-4673-9c6f-3b32eae11279' User entered 'None (1)'	System	13 Sep 2020 16:08:48
	System	13 Sep 2020 16:08:48

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:44', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'bdef565e-6e43-4673-9c6f-3b32eae11279' User entered '13 Sep 2020 12:08'	System	13 Sep 2020 16:08:48
	System	13 Sep 2020 16:08:48

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 4'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:19:55', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ea0a9a73-4da7-46ab-9cce-fc12b9b9ae3f'	System	14 Sep 2020 19:20:15
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	14 Sep 2020 19:20:15

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:19:59', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ea0a9a73-4da7-46ab-9cce-fc12b9b9ae3f' User entered 'No (N)'	System	14 Sep 2020 19:20:15
	System	14 Sep 2020 19:20:15

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:02', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ea0a9a73-4da7-46ab-9cce-fc12b9b9ae3f' User entered 'No (N)'	System	14 Sep 2020 19:20:15
	System	14 Sep 2020 19:20:15

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:08', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ea0a9a73-4da7-46ab-9cce-fc12b9b9ae3f' User entered 'None (1)'	System	14 Sep 2020 19:20:15
	System	14 Sep 2020 19:20:15

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:10', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ea0a9a73-4da7-46ab-9cce-fc12b9b9ae3f' User entered '14 Sep 2020 15:20'	System	14 Sep 2020 19:20:15
	System	14 Sep 2020 19:20:15

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 5'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:43:44', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5de559c3-cb6c-4ba1-95c4-df86d1858793'	System	15 Sep 2020 23:44:09
User entered 'None (1)'	System	15 Sep 2020 23:44:09

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:43:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5de559c3-cb6c-4ba1-95c4-df86d1858793' User entered 'No (N)'	System	15 Sep 2020 23:44:09
	System	15 Sep 2020 23:44:09

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:43:50', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5de559c3-cb6c-4ba1-95c4-df86d1858793' User entered 'No (N)'	System	15 Sep 2020 23:44:09
	System	15 Sep 2020 23:44:09

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:04', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5de559c3-cb6c-4ba1-95c4-df86d1858793'	System	15 Sep 2020 23:44:09
User entered 'None (1)'	System	15 Sep 2020 23:44:09

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:07', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5de559c3-cb6c-4ba1-95c4-df86d1858793' User entered '15 Sep 2020 19:44'	System	15 Sep 2020 23:44:09
	System	15 Sep 2020 23:44:09

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 6'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5401befe-21e8-475a-b236-ffd4bee7f3e1' User entered 'None (1)'	System	16 Sep 2020 23:53:47
	System	16 Sep 2020 23:53:47

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5401befe-21e8-475a-b236-ffd4bee7f3e1' User entered 'No (N)'	System	16 Sep 2020 23:53:47
	System	16 Sep 2020 23:53:47

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:35', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5401befe-21e8-475a-b236-ffd4bee7f3e1' User entered 'No (N)'	System	16 Sep 2020 23:53:47
	System	16 Sep 2020 23:53:47

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:40', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5401befe-21e8-475a-b236-ffd4bee7f3e1' User entered 'None (1)'	System	16 Sep 2020 23:53:47
	System	16 Sep 2020 23:53:47

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:43', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '5401befe-21e8-475a-b236-ffd4bee7f3e1' User entered '16 Sep 2020 19:53'	System	16 Sep 2020 23:53:47
	System	16 Sep 2020 23:53:47

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 7'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:21', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '901187e2-f61d-4e2b-9697-ff03f91ffd0a'	System	18 Sep 2020 03:41:39
User entered 'None (1)'	System	18 Sep 2020 03:41:39

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:25', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '901187e2-f61d-4e2b-9697-ff03f91ffd0a' User entered 'No (N)'	System	18 Sep 2020 03:41:39
	System	18 Sep 2020 03:41:39

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:28', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '901187e2-f61d-4e2b-9697-ff03f91ffd0a' User entered 'No (N)'	System	18 Sep 2020 03:41:39
	System	18 Sep 2020 03:41:39

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:35', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '901187e2-f61d-4e2b-9697-ff03f91ffd0a' User entered 'None (1)'	System	18 Sep 2020 03:41:39
	System	18 Sep 2020 03:41:39

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:38', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '901187e2-f61d-4e2b-9697-ff03f91ffd0a' User entered '17 Sep 2020 23:41'	System	18 Sep 2020 03:41:39
	System	18 Sep 2020 03:41:39

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 14:04'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 16:34'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:19', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd' User entered 'None (0)'	System	12 Sep 2020 00:03:50
	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:25', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd'	System	12 Sep 2020 00:03:50
User entered 'No interference with activity (1)'	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd' User entered 'No interference with activity (1)'	System	12 Sep 2020 00:03:50
	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:32', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd'	System	12 Sep 2020 00:03:50
User entered 'No interference with activity (1)'	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:36', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd' User entered 'None (0)'	System	12 Sep 2020 00:03:50
	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:38', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd' User entered 'None (0)'	System	12 Sep 2020 00:03:50
	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:43', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd' User entered 'No (N)'	System	12 Sep 2020 00:03:50
	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-11T20:03:46', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6b98a3fd-5773-4c82-94f1-f65113caf4bd' User entered '11 Sep 2020 20:03'	System	12 Sep 2020 00:03:50
	System	12 Sep 2020 00:03:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '11 Sep 2020 17:29'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 2'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:04', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8'	System	12 Sep 2020 18:05:57
User entered 'No interference with activity (1)'	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:11', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8'	System	12 Sep 2020 18:05:57
User entered 'Some interference with activity (2)'	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:20', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8'	System	12 Sep 2020 18:05:57
User entered 'Some interference with activity (2)'	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:24', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8'	System	12 Sep 2020 18:05:57
User entered 'Some interference with activity (2)'	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:39', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8'	System	12 Sep 2020 18:05:57
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:43', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8' User entered 'None (0)'	System	12 Sep 2020 18:05:57
	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:49', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8' User entered 'No (N)'	System	12 Sep 2020 18:05:57
	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-12T14:05:52', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '16be48f1-fa84-45ea-8935-1341bd798cc8' User entered '12 Sep 2020 14:05'	System	12 Sep 2020 18:05:57
	System	12 Sep 2020 18:05:57

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 3'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:54', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61'	System	13 Sep 2020 16:10:05
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:08:59', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61'	System	13 Sep 2020 16:10:05
User entered 'Some interference with activity (2)'	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:09:25', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61' User entered 'No interference with activity (1)'	System	13 Sep 2020 16:10:05
	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:09:31', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61' User entered 'No interference with activity (1)'	System	13 Sep 2020 16:10:05
	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:09:47', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61'	System	13 Sep 2020 16:10:05
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:09:50', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61' User entered 'None (0)'	System	13 Sep 2020 16:10:05
	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:09:55', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61' User entered 'No (N)'	System	13 Sep 2020 16:10:05
	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-13T12:09:58', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '19c6d16b-5227-4a61-b7df-e636e2328a61' User entered '13 Sep 2020 12:09'	System	13 Sep 2020 16:10:05
	System	13 Sep 2020 16:10:05

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 4'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:20', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf'	System	14 Sep 2020 19:20:50
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:26', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf'	System	14 Sep 2020 19:20:50
User entered 'Some interference with activity (2)'	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf' User entered 'Some interference with activity (2)'	System	14 Sep 2020 19:20:50
	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf'	System	14 Sep 2020 19:20:50
User entered 'Some interference with activity (2)'	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:37', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf' User entered 'None (0)'	System	14 Sep 2020 19:20:50
	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:42', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf' User entered 'None (0)'	System	14 Sep 2020 19:20:50
	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:46', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf' User entered 'No (N)'	System	14 Sep 2020 19:20:50
	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-14T15:20:49', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1f392ee4-b58c-46b4-aea0-5665f0d16fdf' User entered '14 Sep 2020 15:20'	System	14 Sep 2020 19:20:50
	System	14 Sep 2020 19:20:50

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 5'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:17', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6'	System	15 Sep 2020 23:44:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:22', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6'	System	15 Sep 2020 23:44:51
User entered 'Some interference with activity (2)'	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:27', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6'	System	15 Sep 2020 23:44:51
User entered 'Some interference with activity (2)'	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:31', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6'	System	15 Sep 2020 23:44:51
User entered 'Some interference with activity (2)'	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:34', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6' User entered 'None (0)'	System	15 Sep 2020 23:44:51
	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:38', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6' User entered 'None (0)'	System	15 Sep 2020 23:44:51
	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:42', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6' User entered 'No (N)'	System	15 Sep 2020 23:44:51
	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-15T19:44:45', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '892976cf-b745-4a51-aa9f-412f3950c1f6' User entered '15 Sep 2020 19:44'	System	15 Sep 2020 23:44:51
	System	15 Sep 2020 23:44:51

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 6'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:53:52', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90'	System	16 Sep 2020 23:54:37
User entered 'No interference with activity (1)'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:54:04', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90'	System	16 Sep 2020 23:54:37
User entered 'Some interference with activity (2)'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:54:13', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90'	System	16 Sep 2020 23:54:37
User entered 'No interference with activity (1)'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:54:20', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90'	System	16 Sep 2020 23:54:37
User entered 'No interference with activity (1)'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:54:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90' User entered 'None (0)'	System	16 Sep 2020 23:54:37
	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:54:27', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90' User entered 'None (0)'	System	16 Sep 2020 23:54:37
	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:54:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90'	System	16 Sep 2020 23:54:37
User entered 'No (N)'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-16T19:54:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc47eb2b-609a-4428-8567-92352067de90' User entered '16 Sep 2020 19:54'	System	16 Sep 2020 23:54:37
	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 7'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:44', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346' User entered 'None (0)'	System	18 Sep 2020 03:42:13
	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346'	System	18 Sep 2020 03:42:13
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:52', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346'	System	18 Sep 2020 03:42:13
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:56', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346'	System	18 Sep 2020 03:42:13
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:41:59', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346' User entered 'None (0)'	System	18 Sep 2020 03:42:13
	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:42:02', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346' User entered 'None (0)'	System	18 Sep 2020 03:42:13
	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:42:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346' User entered 'No (N)'	System	18 Sep 2020 03:42:13
	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-17T23:42:09', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26cd613a-8419-4d06-8dc7-c1c61978d346' User entered '17 Sep 2020 23:42'	System	18 Sep 2020 03:42:13
	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	16 Sep 2020 23:54:37
User entered 'Day 8'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:15', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc2dd06c-eea2-4b0a-847e-5a324bc8f615'	System	19 Sep 2020 02:14:24
User entered 'No interference with activity (1)'	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:18', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'dc2dd06c-eea2-4b0a-847e-5a324bc8f615' User entered '18 Sep 2020 22:14'	System	19 Sep 2020 02:14:24
	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	18 Sep 2020 03:42:13
User entered 'Day 9'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Sep 2020 02:14:24
User entered 'Day 10'	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:06', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '268466da-cb8e-4ac2-bdff-0838dd63a63b'	System	20 Sep 2020 20:44:12
User entered 'No interference with activity (1)'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:09', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '268466da-cb8e-4ac2-bdff-0838dd63a63b' User entered '20 Sep 2020 16:44'	System	20 Sep 2020 20:44:12
	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	20 Sep 2020 20:44:12
User entered 'Day 11'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-22T11:07:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '52063f38-1438-4488-bf1e-4f1339b63deb' User entered 'No interference with activity (1)'	System	22 Sep 2020 15:07:39
	System	22 Sep 2020 15:07:39

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-22T11:07:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '52063f38-1438-4488-bf1e-4f1339b63deb' User entered '22 Sep 2020 11:07'	System	22 Sep 2020 15:07:39
	System	22 Sep 2020 15:07:39

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	20 Sep 2020 20:44:12
User entered 'Day 12'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	22 Sep 2020 15:07:39
User entered 'Day 13'	System	22 Sep 2020 15:07:39

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:07:39

US3522666

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:07:39

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	16 Sep 2020 23:54:37
User entered 'Day 8'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:27', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'fa4aaa56-9082-45f2-b690-f1394cbb4b79'	System	19 Sep 2020 02:14:34
User entered 'No interference with activity (1)'	System	19 Sep 2020 02:14:34

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'fa4aaa56-9082-45f2-b690-f1394cbb4b79'	System	19 Sep 2020 02:14:34
User entered '18 Sep 2020 22:14'	System	19 Sep 2020 02:14:34

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	18 Sep 2020 03:42:13
User entered 'Day 9'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Sep 2020 02:14:34
User entered 'Day 10'	System	19 Sep 2020 02:14:34

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:16', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'bd2b2d95-f9b2-4060-81bd-d4a928675464' User entered 'None (0)'	System	20 Sep 2020 20:44:22
	System	20 Sep 2020 20:44:22

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:19', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'bd2b2d95-f9b2-4060-81bd-d4a928675464' User entered '20 Sep 2020 16:44'	System	20 Sep 2020 20:44:22
	System	20 Sep 2020 20:44:22

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 02:14:34

US3522666

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 02:14:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	16 Sep 2020 23:54:37
User entered 'Day 8'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:35', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '90e65b7a-522a-43b0-8f32-5c5bd73e4229'	System	19 Sep 2020 02:14:40
User entered 'No interference with activity (1)'	System	19 Sep 2020 02:14:40

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:38', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '90e65b7a-522a-43b0-8f32-5c5bd73e4229' User entered '18 Sep 2020 22:14'	System	19 Sep 2020 02:14:40
	System	19 Sep 2020 02:14:40

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	18 Sep 2020 03:42:13
User entered 'Day 9'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Sep 2020 02:14:40
User entered 'Day 10'	System	19 Sep 2020 02:14:40

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:28', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '10c83e58-a6af-470a-81f4-1fdc8c127d5b'	System	20 Sep 2020 20:44:34
User entered 'No interference with activity (1)'	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:31', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '10c83e58-a6af-470a-81f4-1fdc8c127d5b' User entered '20 Sep 2020 16:44'	System	20 Sep 2020 20:44:34
	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 02:14:40

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 02:14:40

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	20 Sep 2020 20:44:34
User entered 'Day 11'	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-22T11:07:41', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1a18d2d9-6abe-4c20-ba13-0de2288e26f9'	System	22 Sep 2020 15:07:51
User entered 'No interference with activity (1)'	System	22 Sep 2020 15:07:51

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-22T11:07:44', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1a18d2d9-6abe-4c20-ba13-0de2288e26f9' User entered '22 Sep 2020 11:07'	System	22 Sep 2020 15:07:51
	System	22 Sep 2020 15:07:51

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	20 Sep 2020 20:44:34
User entered 'Day 12'	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 20:44:34

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	22 Sep 2020 15:07:51
User entered 'Day 13'	System	22 Sep 2020 15:07:51

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:07:51

US3522666

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:07:51

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	16 Sep 2020 23:54:37
User entered 'Day 8'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:43', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '10fc17cf-df63-4b96-af48-8cc44fb86e09' User entered 'No (N)'	System	19 Sep 2020 02:14:48
	System	19 Sep 2020 02:14:48

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-18T22:14:46', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '10fc17cf-df63-4b96-af48-8cc44fb86e09'	System	19 Sep 2020 02:14:48
User entered '18 Sep 2020 22:14'	System	19 Sep 2020 02:14:48

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 23:54:37

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	18 Sep 2020 03:42:13
User entered 'Day 9'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:42:13

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Sep 2020 02:14:24
User entered 'Day 10'	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:36', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '769ab389-4ab1-40b9-a411-7d4bde1dcbfb' User entered 'No (N)'	System	20 Sep 2020 20:44:40
	System	20 Sep 2020 20:44:40

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-09-20T16:44:39', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '769ab389-4ab1-40b9-a411-7d4bde1dcbfb' User entered '20 Sep 2020 16:44'	System	20 Sep 2020 20:44:40
	System	20 Sep 2020 20:44:40

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 02:14:24

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
DataPoint Activated.	System	20 Sep 2020 20:44:34
DataPoint Inactivated.	System	20 Sep 2020 20:44:22
Data entry locked.	System	20 Sep 2020 20:44:12
User entered 'Day 11'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
DataPoint Activated.	System	20 Sep 2020 20:44:34
DataPoint Inactivated.	System	20 Sep 2020 20:44:22

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
DataPoint Activated.	System	20 Sep 2020 20:44:34
DataPoint Inactivated.	System	20 Sep 2020 20:44:22

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
DataPoint Activated.	System	20 Sep 2020 20:44:34
DataPoint Inactivated.	System	20 Sep 2020 20:44:22
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
DataPoint Activated.	System	20 Sep 2020 20:44:34
DataPoint Inactivated.	System	20 Sep 2020 20:44:22
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	20 Sep 2020 20:44:12
User entered 'Day 12'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 20:44:12

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	22 Sep 2020 15:07:39
User entered 'Day 13'	System	22 Sep 2020 15:07:39

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:07:39

US3522666

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:07:39

US3522666

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:53
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:29:31

US3522666

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:53
User entered '18 Sep 2020'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:29:31

US3522666

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:53
User entered 'Contact Made (CONTACT MADE)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:29:31

US3522666

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:12:53
User entered 'PT REPORTS PAIN/SORENESS AROUND INJECTION SITE AND NAUSEA 36-48 HOURS AFTER RECEIVING FIRST INJECTION ON 11SEP2020, AND symptoms RESOLVED 17SEP2020. DOES NOT WISH TO SPEAK STUDY DOCTOR' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:29:56
User entered 'Pt reports pain/soreness around injection site and nausea 36-48 hours after receiving first injection on 11Sep2020, and resolved 17Sep2020. Does not wish to speak study doctor'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:29:31

US3522666

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:14:41
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:30:01

US3522666

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'I'	System	18 Sep 2020 16:30:01

US3522666

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:14:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:43:30

US3522666

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:14:50
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:43:30

US3522666

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:14:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 17:43:30

US3522666

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:14:50
User entered 'Patient reporting only continuing AE some joint pain in shoulder, taken motrin, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK.' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:49:11
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4), (b) (6)	25 Sep 2020 17:43:30

US3522666

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:14:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:44:13

US3522666

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:23
User entered 'I'	System	25 Sep 2020 17:44:13

US3522666

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:21:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:40:45

US3522666

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:21:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:40:45

US3522666

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:21:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:40:45

US3522666

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:21:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:12
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:40:45

US3522666

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:21:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:40:51

US3522666

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:21:21
User entered 'I'	System	02 Oct 2020 17:40:51

US3522666

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:49:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:54:05

US3522666

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:49:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:54:05

US3522666

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:49:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:54:05

US3522666

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'VISIT2'	System	12 Oct 2020 13:54:05

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '09:35'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered '12 Oct 2020 09:35'	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '97.1' F	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '67'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'bpm'	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'breaths/min'	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '151'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'mmHg'	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '82'	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'mmHg'	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Oct 2020 14:37:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 14:37:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 14:37:08
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 14:07:36
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '10:32' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered '12 Oct 2020 10:32'	System	12 Oct 2020 14:37:08
User entered empty.	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '97.7' F reason for change: Data Entry Error	(b) (4)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '76' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'bpm'	System	12 Oct 2020 14:37:08
User entered empty.	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'breaths/min'	System	12 Oct 2020 14:37:08
User entered empty.	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '144' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'mmHg'	System	12 Oct 2020 14:37:08
User entered empty.	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:50:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '92' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 14:37:08
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'mmHg'	System	12 Oct 2020 14:37:08
User entered empty.	System	12 Oct 2020 14:07:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:08:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:18
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:08:36

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

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)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '10:02'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered '12 Oct 2020 10:02'	System	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:23
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:23
User entered 'ONCE'	System	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 14:09:14

US3522666

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:42

US3522666

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:42

US3522666

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:27
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '09:53'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:09:42

US3522666

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered '12 Oct 2020 09:53'	System	12 Oct 2020 14:09:42

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:03:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '09:55'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered '12 Oct 2020 09:55'	System	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered empty.	System	12 Oct 2020 14:10:00

US3522666

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:10:06

US3522666

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'I'	System	12 Oct 2020 14:10:06

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 10:22'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 12:52'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:03:52', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a1e82469-857a-4d5a-a175-d6a6c96d2bb8' User entered 'Yes (Y)'	System	13 Oct 2020 10:04:29
	System	13 Oct 2020 10:04:29

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:03:59', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a1e82469-857a-4d5a-a175-d6a6c96d2bb8' User entered '97.7'	System	13 Oct 2020 10:04:29
	System	13 Oct 2020 10:04:29

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:04:19', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a1e82469-857a-4d5a-a175-d6a6c96d2bb8' User entered 'No (N)'	System	13 Oct 2020 10:04:29
	System	13 Oct 2020 10:04:29

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:04:25', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a1e82469-857a-4d5a-a175-d6a6c96d2bb8' User entered '13 Oct 2020 06:04'	System	13 Oct 2020 10:04:29
	System	13 Oct 2020 10:04:29

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 13:47'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 2'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 3'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:04', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1072b7f1-c441-4a49-9cb0-2508f7f7eee4'	System	15 Oct 2020 15:47:24
User entered 'Yes (Y)'	System	15 Oct 2020 15:47:24

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1072b7f1-c441-4a49-9cb0-2508f7f7eee4' User entered '97.6'	System	15 Oct 2020 15:47:24
	System	15 Oct 2020 15:47:24

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:18', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1072b7f1-c441-4a49-9cb0-2508f7f7eee4'	System	15 Oct 2020 15:47:24
User entered 'No (N)'	System	15 Oct 2020 15:47:24

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:22', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '1072b7f1-c441-4a49-9cb0-2508f7f7eee4'	System	15 Oct 2020 15:47:24
User entered '15 Oct 2020 11:47'	System	15 Oct 2020 15:47:24

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 4'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 5'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:06:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '08098555-180d-4b8a-9ab9-396c784f68c0' User entered 'Yes (Y)'	System	17 Oct 2020 06:06:50
	System	17 Oct 2020 06:06:50

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:06:39', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '08098555-180d-4b8a-9ab9-396c784f68c0' User entered '97.5'	System	17 Oct 2020 06:06:50
	System	17 Oct 2020 06:06:50

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:06:45', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '08098555-180d-4b8a-9ab9-396c784f68c0' User entered 'No (N)'	System	17 Oct 2020 06:06:50
	System	17 Oct 2020 06:06:50

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:06:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '08098555-180d-4b8a-9ab9-396c784f68c0' User entered '17 Oct 2020 02:06'	System	17 Oct 2020 06:06:50
	System	17 Oct 2020 06:06:50

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 6'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 7'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:28', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2e7ac99e-eb15-419a-8589-49ff2db12ad3'	System	19 Oct 2020 13:47:45
User entered 'Yes (Y)'	System	19 Oct 2020 13:47:45

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:34', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2e7ac99e-eb15-419a-8589-49ff2db12ad3' User entered '97.6'	System	19 Oct 2020 13:47:45
	System	19 Oct 2020 13:47:45

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:37', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2e7ac99e-eb15-419a-8589-49ff2db12ad3'	System	19 Oct 2020 13:47:45
User entered 'No (N)'	System	19 Oct 2020 13:47:45

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:42', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2e7ac99e-eb15-419a-8589-49ff2db12ad3'	System	19 Oct 2020 13:47:45
User entered '19 Oct 2020 09:47'	System	19 Oct 2020 13:47:45

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 10:22'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 12:52'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:04:55', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '554519dd-009f-4a97-b52c-d512e3eb94e2'	System	13 Oct 2020 10:06:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	13 Oct 2020 10:06:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:05:01', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '554519dd-009f-4a97-b52c-d512e3eb94e2' User entered 'Yes (Y)'	System	13 Oct 2020 10:06:52
	System	13 Oct 2020 10:06:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:05:35', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '554519dd-009f-4a97-b52c-d512e3eb94e2' User entered '5'	System	13 Oct 2020 10:06:52
	System	13 Oct 2020 10:06:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:05:43', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '554519dd-009f-4a97-b52c-d512e3eb94e2' User entered 'Yes (Y)'	System	13 Oct 2020 10:06:52
	System	13 Oct 2020 10:06:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:06:09', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '554519dd-009f-4a97-b52c-d512e3eb94e2' User entered '1'	System	13 Oct 2020 10:06:52
	System	13 Oct 2020 10:06:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:06:22', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '554519dd-009f-4a97-b52c-d512e3eb94e2'	System	13 Oct 2020 10:06:52
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 10:06:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:06:46', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '554519dd-009f-4a97-b52c-d512e3eb94e2' User entered '13 Oct 2020 06:06'	System	13 Oct 2020 10:06:52
	System	13 Oct 2020 10:06:52

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 13:47'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 2'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 3'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2ec88376-ff3d-4a91-a660-abbf2ab0177d' User entered 'None (1)'	System	15 Oct 2020 15:47:55
	System	15 Oct 2020 15:47:55

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:38', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2ec88376-ff3d-4a91-a660-abbf2ab0177d' User entered 'No (N)'	System	15 Oct 2020 15:47:55
	System	15 Oct 2020 15:47:55

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:41', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2ec88376-ff3d-4a91-a660-abbf2ab0177d' User entered 'No (N)'	System	15 Oct 2020 15:47:55
	System	15 Oct 2020 15:47:55

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2ec88376-ff3d-4a91-a660-abbf2ab0177d' User entered 'None (1)'	System	15 Oct 2020 15:47:55
	System	15 Oct 2020 15:47:55

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:47:51', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '2ec88376-ff3d-4a91-a660-abbf2ab0177d' User entered '15 Oct 2020 11:47'	System	15 Oct 2020 15:47:55
	System	15 Oct 2020 15:47:55

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 4'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 5'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:06:53', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26d03647-0620-42cd-ac7d-afcece1f86c2'	System	17 Oct 2020 06:07:16
User entered 'None (1)'	System	17 Oct 2020 06:07:16

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:06:59', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26d03647-0620-42cd-ac7d-afcece1f86c2'	System	17 Oct 2020 06:07:16
User entered 'No (N)'	System	17 Oct 2020 06:07:16

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:03', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26d03647-0620-42cd-ac7d-afcece1f86c2'	System	17 Oct 2020 06:07:16
User entered 'No (N)'	System	17 Oct 2020 06:07:16

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:11', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26d03647-0620-42cd-ac7d-afcece1f86c2'	System	17 Oct 2020 06:07:16
User entered 'None (1)'	System	17 Oct 2020 06:07:16

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:13', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '26d03647-0620-42cd-ac7d-afcece1f86c2' User entered '17 Oct 2020 02:07'	System	17 Oct 2020 06:07:16
	System	17 Oct 2020 06:07:16

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 6'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 7'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '15c56db5-60b8-4424-8c5a-14901e353b5e' User entered 'None (1)'	System	19 Oct 2020 13:48:06
	System	19 Oct 2020 13:48:06

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:51', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '15c56db5-60b8-4424-8c5a-14901e353b5e' User entered 'No (N)'	System	19 Oct 2020 13:48:06
	System	19 Oct 2020 13:48:06

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:54', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '15c56db5-60b8-4424-8c5a-14901e353b5e' User entered 'No (N)'	System	19 Oct 2020 13:48:06
	System	19 Oct 2020 13:48:06

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:47:58', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '15c56db5-60b8-4424-8c5a-14901e353b5e' User entered 'None (1)'	System	19 Oct 2020 13:48:06
	System	19 Oct 2020 13:48:06

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:01', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '15c56db5-60b8-4424-8c5a-14901e353b5e' User entered '19 Oct 2020 09:48'	System	19 Oct 2020 13:48:06
	System	19 Oct 2020 13:48:06

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:26:41', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8' User entered 'None (0)'	System	12 Oct 2020 14:27:15
	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:26:44', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8' User entered 'None (0)'	System	12 Oct 2020 14:27:15
	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:26:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8' User entered 'None (0)'	System	12 Oct 2020 14:27:15
	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:26:53', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8'	System	12 Oct 2020 14:27:15
User entered 'No interference with activity (1)'	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:26:56', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8' User entered 'None (0)'	System	12 Oct 2020 14:27:15
	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:27:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8' User entered 'None (0)'	System	12 Oct 2020 14:27:15
	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:27:07', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8' User entered 'No (N)'	System	12 Oct 2020 14:27:15
	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-12T10:27:12', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8e93847-b8d2-4e3d-b5c4-a88d20ee87f8' User entered '12 Oct 2020 10:27'	System	12 Oct 2020 14:27:15
	System	12 Oct 2020 14:27:15

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 10:22'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 12:52'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:06:59', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc'	System	13 Oct 2020 10:07:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:07:06', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc'	System	13 Oct 2020 10:07:51
User entered 'Significant; prevents daily activity (3)'	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:07:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc'	System	13 Oct 2020 10:07:51
User entered 'Significant; prevents daily activity (3)'	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:07:21', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc'	System	13 Oct 2020 10:07:51
User entered 'Some interference with activity (2)'	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:07:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc'	System	13 Oct 2020 10:07:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:07:36', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc'	System	13 Oct 2020 10:07:51
User entered 'No interference with activity (1)'	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:07:42', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc' User entered 'No (N)'	System	13 Oct 2020 10:07:51
	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-13T06:07:45', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '41fb0cf9-df74-4c59-8bed-9644c5a8bddc' User entered '13 Oct 2020 06:07'	System	13 Oct 2020 10:07:51
	System	13 Oct 2020 10:07:51

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '12 Oct 2020 13:47'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 2'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 3'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d'	System	15 Oct 2020 15:48:43
User entered 'No interference with activity (1)'	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:07', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d'	System	15 Oct 2020 15:48:43
User entered 'Some interference with activity (2)'	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:12', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d'	System	15 Oct 2020 15:48:43
User entered 'No interference with activity (1)'	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:17', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d'	System	15 Oct 2020 15:48:43
User entered 'No interference with activity (1)'	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:28', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d' User entered 'None (0)'	System	15 Oct 2020 15:48:43
	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:32', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d' User entered 'None (0)'	System	15 Oct 2020 15:48:43
	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:36', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d' User entered 'No (N)'	System	15 Oct 2020 15:48:43
	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-15T11:48:39', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'a074aca3-c57f-4ec6-9c2c-678a54007c0d' User entered '15 Oct 2020 11:48'	System	15 Oct 2020 15:48:43
	System	15 Oct 2020 15:48:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 4'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 5'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:20', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7'	System	17 Oct 2020 06:07:59
User entered 'No interference with activity (1)'	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7'	System	17 Oct 2020 06:07:59
User entered 'Some interference with activity (2)'	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7'	System	17 Oct 2020 06:07:59
User entered 'No interference with activity (1)'	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:40', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7' User entered 'No interference with activity (1)'	System	17 Oct 2020 06:07:59
	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:46', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7'	System	17 Oct 2020 06:07:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:50', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7' User entered 'None (0)'	System	17 Oct 2020 06:07:59
	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:54', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7' User entered 'No (N)'	System	17 Oct 2020 06:07:59
	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-17T02:07:57', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'eba82fd0-95ae-4603-b0d8-37828a8eeec7' User entered '17 Oct 2020 02:07'	System	17 Oct 2020 06:07:59
	System	17 Oct 2020 06:07:59

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 6'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	12 Oct 2020 14:09:14
User entered 'Day 7'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:08', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4' User entered 'None (0)'	System	19 Oct 2020 13:48:36
	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:12', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4'	System	19 Oct 2020 13:48:36
User entered 'No interference with activity (1)'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:16', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4'	System	19 Oct 2020 13:48:36
User entered 'No interference with activity (1)'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:20', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4'	System	19 Oct 2020 13:48:36
User entered 'No interference with activity (1)'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:24', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4'	System	19 Oct 2020 13:48:36
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:27', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4' User entered 'None (0)'	System	19 Oct 2020 13:48:36
	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4' User entered 'No (N)'	System	19 Oct 2020 13:48:36
	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-10-19T09:48:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4d7b30e4-65fa-4e3a-8bd8-b76efef99de4' User entered '19 Oct 2020 09:48'	System	19 Oct 2020 13:48:36
	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 14:09:14

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 8'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 9'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 8'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 9'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 8'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 9'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 8'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 9'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:03:14

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 8'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '19 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	19 Oct 2020 13:48:36
User entered 'Day 9'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

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)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 13:48:36

US3522666

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:03:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 13:48:36

US3522666

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:41
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:59:03

US3522666

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:41
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '20 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	20 Oct 2020 14:14:48
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 18:59:03

US3522666

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:41
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	(b) (4), (b) (6)	20 Oct 2020 14:14:48
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	19 Oct 2020 18:59:03

US3522666

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:41
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'See source. No new illness or hospital visits; no changes in health status, medications, Covid-19 exposure.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:14:48
User entered 'call attempted; voicemail left with return contact information.'	(b) (4), (b) (6)	19 Oct 2020 18:59:03

US3522666

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 14:25:00

US3522666

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'I'	System	20 Oct 2020 14:25:00

US3522666

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:52
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 15:46:55

US3522666

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:52
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:46:55

US3522666

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:52
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Oct 2020 15:46:55

US3522666

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:52
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:46:55

US3522666

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:26:55
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:47:00

US3522666

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'I'	System	26 Oct 2020 15:47:00

US3522666

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:27:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 18:19:23

US3522666

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:27:26
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 20:40:54
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 18:19:23

US3522666

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:27:28
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Kristin Eis (b) (4)	03 Nov 2020 20:40:54
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 18:19:23

US3522666

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 02:03:55
User closed query 'Please either leave blank or update comment to call details as seen in source.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 02:03:53
Query 'Please either leave blank or update comment to call details as seen in source.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:22:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 16:21:50
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Apr 2021 16:21:50
User opened query 'Please either leave blank or update comment to call details as seen in source.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 13:27:58
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'patient did not answer; voicemail was left' reason for change: Data Entry Error	Kristin Eis (b) (4)	03 Nov 2020 20:40:54
User entered 'left voicemail with contact information and email'	(b) (4), (b) (6)	02 Nov 2020 18:19:23

US3522666

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:28:10
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	Kristin Eis (b) (4)	03 Nov 2020 20:41:03

US3522666

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'I'	System	03 Nov 2020 20:41:03

US3522666

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:15

US3522666

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '9 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:15

US3522666

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:53:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:15

US3522666

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'VISIT3'	System	09 Nov 2020 16:14:15

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:22:52
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'updated format' (Site from DM).	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:26:05
User entered '09 Nov 2020' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:25:48
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 11:05:23
User entered '9 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '11:00'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered '09 Nov 2020 11:00'	System	12 Nov 2020 15:25:48
User entered '9 Nov 2020 11:00'	System	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '98.0' F	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '76'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'bpm'	System	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '20'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'breaths/min'	System	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '149'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'mmHg'	System	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '66'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'mmHg'	System	09 Nov 2020 16:14:48

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14

US3522666

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14

US3522666

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:56

US3522666

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '9 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:14:56

US3522666

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:15:06

US3522666

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '9 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:15:06

US3522666

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:22
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered '11:10'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:15:06

US3522666

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered '9 Nov 2020 11:10'	System	09 Nov 2020 16:15:06

US3522666

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:25
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Nov 2020 16:15:11

US3522666

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:45:14
User entered 'I'	System	09 Nov 2020 16:15:11

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 64'	System	11 Sep 2020 18:25:29

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-11-13T16:42:36', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '599eb584-1773-48e6-963c-623fe3b4a95a'	System	13 Nov 2020 21:42:45
User entered 'No (N)'	System	13 Nov 2020 21:42:45

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-11-13T16:42:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '599eb584-1773-48e6-963c-623fe3b4a95a'	System	13 Nov 2020 21:42:45
User entered 'No (N)'	System	13 Nov 2020 21:42:45

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-11-13T16:42:42', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '599eb584-1773-48e6-963c-623fe3b4a95a' User entered '13 Nov 2020 16:42:42'	System	13 Nov 2020 21:42:45
	System	13 Nov 2020 21:42:45

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 18:25:29

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:43
Data entry locked.	System	11 Sep 2020 18:25:29
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36
Data entry locked.	System	11 Sep 2020 18:25:29
User entered 'Day 71'	System	11 Sep 2020 18:25:29

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36
Data entry locked.	System	11 Sep 2020 18:25:29
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 18:25:29

US3522666

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:41:36
Data entry locked.	System	11 Sep 2020 18:25:29
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 18:25:29

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:15:16', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered 'Yes (Y)'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:15:25', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered 'No (N)'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:15:52', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered 'Yes (Y)'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9'	System	03 Dec 2020 20:17:20
User entered '0'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9'	System	03 Dec 2020 20:17:20
User entered '1'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9'	System	03 Dec 2020 20:17:20
User entered '0'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9'	System	03 Dec 2020 20:17:20
User entered '1'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9'	System	03 Dec 2020 20:17:20
User entered '0'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9'	System	03 Dec 2020 20:17:20
User entered '0'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:29', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '0'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:16:45', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9'	System	03 Dec 2020 20:17:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:17:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered 'No (N)'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-03T15:17:11', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'aacf5b74-cfd9-41b4-939d-d2f57ab11fa9' User entered '03 Dec 2020 15:17:11'	System	03 Dec 2020 20:17:20
	System	03 Dec 2020 20:17:20

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-10T12:47:50', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6747ab32-a8c1-46cf-971b-05dad4b8739b' User entered 'No (N)'	System	10 Dec 2020 17:48:16
	System	10 Dec 2020 17:48:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-10T12:47:59', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6747ab32-a8c1-46cf-971b-05dad4b8739b' User entered 'No (N)'	System	10 Dec 2020 17:48:16
	System	10 Dec 2020 17:48:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-10T12:48:11', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '6747ab32-a8c1-46cf-971b-05dad4b8739b' User entered '10 Dec 2020 12:48:11'	System	10 Dec 2020 17:48:16
	System	10 Dec 2020 17:48:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-13T11:28:32', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ed2cf40e-6062-484d-81b6-bb2a40e01d7f' User entered 'No (N)'	System	13 Dec 2020 16:29:03
	System	13 Dec 2020 16:29:03

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-13T11:28:55', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ed2cf40e-6062-484d-81b6-bb2a40e01d7f' User entered 'No (N)'	System	13 Dec 2020 16:29:03
	System	13 Dec 2020 16:29:03

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-13T11:29:01', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'ed2cf40e-6062-484d-81b6-bb2a40e01d7f' User entered '13 Dec 2020 11:29:01'	System	13 Dec 2020 16:29:03
	System	13 Dec 2020 16:29:03

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-23T18:01:44', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd1db6840-9f45-418b-bcff-7acffa36e47f' User entered 'No (N)'	System	23 Dec 2020 23:01:57
	System	23 Dec 2020 23:01:57

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-23T18:01:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd1db6840-9f45-418b-bcff-7acffa36e47f' User entered 'No (N)'	System	23 Dec 2020 23:01:57
	System	23 Dec 2020 23:01:57

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-23T18:01:53', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd1db6840-9f45-418b-bcff-7acffa36e47f' User entered '23 Dec 2020 18:01:53'	System	23 Dec 2020 23:01:57
	System	23 Dec 2020 23:01:57

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-27T00:01:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f3d27e24-67cb-47bb-b734-d4ef74817a10' User entered 'No (N)'	System	27 Dec 2020 05:02:16
	System	27 Dec 2020 05:02:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-27T00:01:53', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f3d27e24-67cb-47bb-b734-d4ef74817a10' User entered 'No (N)'	System	27 Dec 2020 05:02:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2020-12-27T00:01:57', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f3d27e24-67cb-47bb-b734-d4ef74817a10' User entered '27 Dec 2020 00:01:57'	System	27 Dec 2020 05:02:16
	System	27 Dec 2020 05:02:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-07T22:48:34', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4c1eb78a-2f0c-4c43-8608-fc799b4efcf6'	System	08 Jan 2021 03:48:50
User entered 'No (N)'	System	08 Jan 2021 03:48:50

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-07T22:48:42', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4c1eb78a-2f0c-4c43-8608-fc799b4efcf6' User entered 'No (N)'	System	08 Jan 2021 03:48:50

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-07T22:48:46', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '4c1eb78a-2f0c-4c43-8608-fc799b4efcf6' User entered '07 Jan 2021 22:48:46'	System	08 Jan 2021 03:48:50

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-13T17:59:48', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3d09f1b2-f951-4a05-89c2-eddb04733fd3' User entered 'No (N)'	System	13 Jan 2021 23:00:02

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-13T17:59:52', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3d09f1b2-f951-4a05-89c2-eddb04733fd3'	System	13 Jan 2021 23:00:02
User entered 'No (N)'	System	13 Jan 2021 23:00:02

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-13T17:59:56', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3d09f1b2-f951-4a05-89c2-eddb04733fd3' User entered '13 Jan 2021 17:59:56'	System	13 Jan 2021 23:00:02

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-21T13:56:03', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f704067a-58d9-4aa6-9b5f-31fcc2731e60'	System	21 Jan 2021 18:56:17
User entered 'No (N)'	System	21 Jan 2021 18:56:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-21T13:56:07', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f704067a-58d9-4aa6-9b5f-31fcc2731e60' User entered 'No (N)'	System	21 Jan 2021 18:56:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-21T13:56:13', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f704067a-58d9-4aa6-9b5f-31fcc2731e60' User entered '21 Jan 2021 13:56:13'	System	21 Jan 2021 18:56:17
	System	21 Jan 2021 18:56:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:16:06', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febfcf2-1b09-40ba-9eea-c67d02b4c94a' User entered 'Yes (Y)'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:16:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febfcf2-1b09-40ba-9eea-c67d02b4c94a' User entered 'No (N)'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:13:55', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febfcf2-1b09-40ba-9eea-c67d02b4c94a' User entered 'Yes (Y)'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a' User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '1'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '1'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '1'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febfcf2-1b09-40ba-9eea-c67d02b4c94a' User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a' User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a' User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a' User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a' User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a' User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:14:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered '0'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:15:21', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febfcf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:15:34', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febfcf2-1b09-40ba-9eea-c67d02b4c94a' User entered 'Yes (Y)'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:15:40', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febfcf2-1b09-40ba-9eea-c67d02b4c94a'	System	24 Jan 2021 05:16:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-01-24T00:16:09', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '3febf2-1b09-40ba-9eea-c67d02b4c94a' User entered '24 Jan 2021 00:16:09'	System	24 Jan 2021 05:16:17

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-04T11:59:42', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'cfd854b3-14fd-4737-b6b6-563a1f51acab' User entered 'No (N)'	System	04 Feb 2021 16:59:56
	System	04 Feb 2021 16:59:56

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-04T11:59:47', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'cfd854b3-14fd-4737-b6b6-563a1f51acab' User entered 'No (N)'	System	04 Feb 2021 16:59:56
	System	04 Feb 2021 16:59:56

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-04T11:59:53', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'cfd854b3-14fd-4737-b6b6-563a1f51acab' User entered '04 Feb 2021 11:59:53'	System	04 Feb 2021 16:59:56
	System	04 Feb 2021 16:59:56

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T09:51:43', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered 'Yes (Y)'	System	09 Feb 2021 15:07:45
	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T09:51:53', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered 'No (N)'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:06:30', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered 'Yes (Y)'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered '1'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '1'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered '0'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:05', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '1'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:14', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:23', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af' User entered 'No (N)'	System	09 Feb 2021 15:07:45
	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-09T10:07:34', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f8f100ef-7fbd-4721-b984-c24a680fe9af'	System	09 Feb 2021 15:07:45
User entered '09 Feb 2021 10:07:34'	System	09 Feb 2021 15:07:45

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-18T09:50:22', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f60a7ad3-c35e-4962-8678-344fc9892606'	System	18 Feb 2021 14:50:30
User entered 'No (N)'	System	18 Feb 2021 14:50:30

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-18T09:50:25', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f60a7ad3-c35e-4962-8678-344fc9892606' User entered 'No (N)'	System	18 Feb 2021 14:50:30
	System	18 Feb 2021 14:50:30

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-18T09:50:28', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f60a7ad3-c35e-4962-8678-344fc9892606' User entered '18 Feb 2021 09:50:28'	System	18 Feb 2021 14:50:30
	System	18 Feb 2021 14:50:30

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-21T00:01:33', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f7302712-4315-4f0b-a1ae-0aac5d36522f' User entered 'No (N)'	System	21 Feb 2021 05:02:37

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-21T00:01:36', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f7302712-4315-4f0b-a1ae-0aac5d36522f' User entered 'No (N)'	System	21 Feb 2021 05:02:37

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-02-21T00:01:39', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'f7302712-4315-4f0b-a1ae-0aac5d36522f' User entered '21 Feb 2021 00:01:39'	System	21 Feb 2021 05:02:37
	System	21 Feb 2021 05:02:37

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-11T16:22:25-05:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'df28d188-2836-4191-8f4f-25a5873d3d23'	System	11 Mar 2021 21:22:39
User entered 'No (N)'	System	11 Mar 2021 21:22:39

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-11T16:22:29-05:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'df28d188-2836-4191-8f4f-25a5873d3d23'	System	11 Mar 2021 21:22:39
User entered 'No (N)'	System	11 Mar 2021 21:22:39

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-11T16:22:33-05:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'df28d188-2836-4191-8f4f-25a5873d3d23'	System	11 Mar 2021 21:22:39
User entered '11 Mar 2021 16:22:33'	System	11 Mar 2021 21:22:39

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:29:11-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered 'Yes (Y)'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:29:25-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered 'No (N)'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:29:47-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered 'Yes (Y)'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '1'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '1'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '1'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '1'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '1'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '1'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:43-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '0'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:30:54-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:31:04-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered 'Yes (Y)'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:31:10-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-23T01:31:15-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'd2ec5b09-ebe5-4dd6-b7a2-3ecc73916ca5'	System	23 Mar 2021 05:31:26
User entered '23 Mar 2021 01:31:15'	System	23 Mar 2021 05:31:26

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-01T13:22:30-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '0bc8e176-a1e6-4673-8313-0f3d164d5c26'	System	01 Apr 2021 17:23:16
User entered 'Yes (Y)'	System	01 Apr 2021 17:23:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-01T13:22:35-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '0bc8e176-a1e6-4673-8313-0f3d164d5c26'	System	01 Apr 2021 17:23:16
User entered 'No (N)'	System	01 Apr 2021 17:23:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-01T13:22:41-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '0bc8e176-a1e6-4673-8313-0f3d164d5c26'	System	01 Apr 2021 17:23:16
User entered 'No (N)'	System	01 Apr 2021 17:23:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-01T13:22:54-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '0bc8e176-a1e6-4673-8313-0f3d164d5c26'	System	01 Apr 2021 17:23:16
User entered 'Yes (Y)'	System	01 Apr 2021 17:23:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-01T13:22:58-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '0bc8e176-a1e6-4673-8313-0f3d164d5c26'	System	01 Apr 2021 17:23:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Apr 2021 17:23:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-01T13:23:02-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '0bc8e176-a1e6-4673-8313-0f3d164d5c26' User entered '01 Apr 2021 13:23:02'	System	01 Apr 2021 17:23:16
	System	01 Apr 2021 17:23:16

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-08T17:58:03-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c5d4a0c5-3867-4224-9ebd-697ba2eb20a2'	System	08 Apr 2021 21:58:47
User entered 'Yes (Y)'	System	08 Apr 2021 21:58:47

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-08T17:58:08-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c5d4a0c5-3867-4224-9ebd-697ba2eb20a2' User entered 'No (N)'	System	08 Apr 2021 21:58:47

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-08T17:58:14-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c5d4a0c5-3867-4224-9ebd-697ba2eb20a2'	System	08 Apr 2021 21:58:47
User entered 'No (N)'	System	08 Apr 2021 21:58:47

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-08T17:58:20-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c5d4a0c5-3867-4224-9ebd-697ba2eb20a2'	System	08 Apr 2021 21:58:47
User entered 'Yes (Y)'	System	08 Apr 2021 21:58:47

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Please 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-08T17:58:26-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c5d4a0c5-3867-4224-9ebd-697ba2eb20a2'	System	08 Apr 2021 21:58:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Apr 2021 21:58:47

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-08T17:58:30-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'c5d4a0c5-3867-4224-9ebd-697ba2eb20a2' User entered '08 Apr 2021 17:58:30'	System	08 Apr 2021 21:58:47

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-15T15:15:19-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '97eec8c0-d77e-4725-a272-391e42ea26db' User entered 'No (N)'	System	15 Apr 2021 19:15:39

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-15T15:15:25-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '97eec8c0-d77e-4725-a272-391e42ea26db' User entered 'No (N)'	System	15 Apr 2021 19:15:39

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-15T15:15:35-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: '97eec8c0-d77e-4725-a272-391e42ea26db' User entered '15 Apr 2021 15:15:35'	System	15 Apr 2021 19:15:39
	System	15 Apr 2021 19:15:39

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-22T23:05:48-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'af46f4e0-5d8e-491f-8285-21dd2ffe7668'	System	23 Apr 2021 03:06:04
User entered 'No (N)'	System	23 Apr 2021 03:06:04

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Have you been exposed to someone with 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 (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-22T23:05:55-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'af46f4e0-5d8e-491f-8285-21dd2ffe7668'	System	23 Apr 2021 03:06:04
User entered 'No (N)'	System	23 Apr 2021 03:06:04

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-04-22T23:05:58-04:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'af46f4e0-5d8e-491f-8285-21dd2ffe7668'	System	23 Apr 2021 03:06:04
User entered '22 Apr 2021 23:05:58'	System	23 Apr 2021 03:06:04

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:41:36

US3522666

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:41:36
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:41:36

US3522666

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-11T16:22:41-05:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'b0c24ae9-89a6-4085-91d1-d5c2161b6c6f' User entered 'No (N)'	System	11 Mar 2021 21:22:49
	System	11 Mar 2021 21:22:49

US3522666

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3392089-828A-4E5C-8DD9-D77CEF8A1B39)', Time: '2021-03-11T16:22:45-05:00', User OID: 'PatientReportedOutcome (US3522666)', ODM File OID: 'b0c24ae9-89a6-4085-91d1-d5c2161b6c6f' User entered '11 Mar 2021 16:22:45'	System	11 Mar 2021 21:22:49
	System	11 Mar 2021 21:22:49

US3522666

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:28:28
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:54:20

US3522666

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:28:28
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:54:20

US3522666

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:28:28
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:54:20

US3522666

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:28:28
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'See source'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:54:20

US3522666

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:31:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:54:24

US3522666

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:40
User entered 'I'	System	07 Dec 2020 20:54:24

US3522666

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:31:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:47:44

US3522666

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:31:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '9 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:47:44

US3522666

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:31:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:47:44

US3522666

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:31:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'left vm'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:47:44

US3522666

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:31:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:48:06

US3522666

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
User entered 'I'	System	09 Feb 2021 14:48:06

US3522666

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:32:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:52:46

US3522666

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:32:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 16:24:51
User entered '9 Feb 2021'	Yaman Ahmed (b) (4)	09 Feb 2021 14:52:46

US3522666

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:32:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 16:24:51
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4)	09 Feb 2021 14:52:46
	(b) (4)	

US3522666

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Data hard locked.	(b) (4)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:50:47
User closed query 'Please review source note and enter: Per phone call on 10Feb2021, Subject reported COVID related symptoms that started on 06Feb2021 and lasted for at least 48hours.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 19:50:44
Query 'Please review source note and enter: Per phone call on 10Feb2021, Subject reported COVID related symptoms that started on 06Feb2021 and lasted for at least 48hours.' answered with 'reviewed, added suggested text' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:24:15
User entered 'PER PHONE CALL 10FEB2021, SUBJECT REPORTED COVID RELATED SYMPTOMS THAT STARTED 06FEB2021, LASTED FOR AT LEAST 48HOURS.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:23:04
User entered 'PER PHONE CALL ON 10FEB2021, SUBJECT REPORTED COVID RELATED SYMPTOMS THAT STARTED ON 06FEB2021, LASTED FOR AT LEAST 48HOURS.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:22:15
User entered 'PER PHONE CALL ON 10FEB2021, SUBJECT REPORTED COVID RELATED SYMPTOMS THAT STARTED ON 06FEB2021 AND LASTED FOR AT LEAST 48HOURS.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:21:54
User entered 'SEE SOURCE FOR DETAILS OF CALL. PER PHONE CALL ON 10FEB2021, SUBJECT REPORTED COVID RELATED SYMPTOMS THAT STARTED ON 06FEB2021 AND LASTED FOR AT LEAST 48HOURS.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:21:47
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 13:21:35
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:21:35

US3522666

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'SEE SOURCE FOR DETAILS OF CALL. Per phone call on 10-Feb-2021, Subject reported COVID related symptoms that started on 06-Feb-2021 and lasted for at least 48hours.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:21:35
User opened query 'Please review source note and enter: Per phone call on 10Feb2021, Subject reported COVID related symptoms that started on 06Feb2021 and lasted for at least 48hours.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 02:06:00
User closed query 'Per phone call on 10Feb2021, Subject reported COVID related symptoms that started on 06Feb2021 and lasted for at least 48hours. However, there is no corresponding illness visit arranged within 72 hours. Please kindly advise and clarify.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 02:06:00
Query 'Per phone call on 10Feb2021, Subject reported COVID related symptoms that started on 06Feb2021 and lasted for at least 48hours. However, there is no corresponding illness visit arranged within 72 hours. Please kindly advise and clarify.' answered with 'already noted to document as a deviation, answered as such for previous queries.' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	13 Apr 2021 16:12:02
User opened query 'Per phone call on 10Feb2021, Subject reported COVID related symptoms that started on 06Feb2021 and lasted for at least 48hours. However, there is no corresponding illness visit arranged within 72 hours. Please kindly advise and clarify.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 13:39:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:32:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 19:22:06
User entered 'See source for details of call.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 16:24:51
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:52:46

US3522666

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 02:06:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 16:25:04

US3522666

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
User entered 'I'	System	10 Feb 2021 16:25:04

US3522666

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:09
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:19:31

US3522666

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:09
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '9 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:19:31

US3522666

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:09
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	09 Mar 2021 21:09:50
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 19:19:31
	(b) (4)	

US3522666

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:09
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'CHEMICAL CARDIAC STRESS TEST A MONTH AGO WHICH WAS ABNORMAL SO SCHEDULED FOR CARDIAC CATHERIZATION ON 12 MAR 2021. OTHERWISE, NO AES REPORTED, NO OTHER CHANGES IN HEALTH STATUS, NO COVID-19 EXPOSURE.' reason for change: New Information	Yaman Ahmed (b) (4)	09 Mar 2021 21:10:28
User entered 'Had chemical cardiac stress test a month ago which was abnormal so is scheduled for cardiac catheterization on 12 Mar 2021. Otherwise, no AEs reported, no other changes in health status, no covid-19 exposure.' (non-conformant).	Yaman Ahmed (b) (4)	09 Mar 2021 21:09:50
User entered 'left a voicemail'	Yaman Ahmed (b) (4)	09 Mar 2021 19:19:31

US3522666

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:41
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 21:10:32

US3522666

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:43
User entered 'I'	System	09 Mar 2021 21:10:32

US3522666

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 17:19:09

US3522666

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 17:19:09

US3522666

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:54:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Jan 2021 17:19:09

US3522666

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

Form: Visit Date

Generated On: 10 Jun 2021 08:03:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 17:19:09

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:53:01

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:53:01

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4)	18 Jan 2021 17:19:43
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered by data change (Site from System).	System	18 Jan 2021 17:19:43
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 17:19:43
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	18 Jan 2021 17:19:32
User entered '18 Jan 2020'	(b) (4), (b) (6)	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 09:23:52
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 09:23:52
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
User entered empty.	System	18 Jan 2021 17:19:32

US3522666

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

Form: Unblinding

Generated On: 10 Jun 2021 08:03:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
User entered empty.	System	18 Jan 2021 17:19:32

US3522666

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 17:45:44

US3522666

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 17:45:44

US3522666

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '12:32'	(b) (4), (b) (6)	18 Jan 2021 17:45:44

US3522666

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
User entered '18 Jan 2021 12:32'	System	18 Jan 2021 17:45:44

US3522666

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 17:46:01

US3522666

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 17:46:01

US3522666

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:55:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '12:35'	(b) (4), (b) (6)	18 Jan 2021 17:46:01

US3522666

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:45:13
User entered '18 Jan 2021 12:35'	System	18 Jan 2021 17:46:01

US3522666

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:03:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per review, while subject was in hospital admission, it was also stated that subject had Leukocytosis (likely reactive). Please update and include in database.' (Site from CRA).	(b) (4), (b) (6)	04 May 2021 01:54:37
Query 'Per review, while subject was in hospital admission, it was also stated that subject had Leukocytosis (likely reactive). Please update and include in database.' answered with 'per dr ramesh, a normal result of such surgery, NCS' (Site from CRA).	(b) (4), (b) (6)	03 May 2021 22:34:09
Query 'Per DM CLR RQ: Response noted, however note that per Diary dose 1, Fatigue, Muscle aches all over and Joint aches in several joints was started on 11 Sept2020. Please reconcile and update start date of AE recorded accordingly or else clarify.' answered with 'We were told to combine grades so it's only the combined grade that goes into the original 7 day diary' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:09:29
User opened query 'Per DM CLR RQ: Response noted, however note that per Diary dose 1, Fatigue, Muscle aches all over and Joint aches in several joints was started on 11 Sept2020. Please reconcile and update start date of AE recorded accordingly or else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 03:39:41
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 03:39:41

US3522666

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:03:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'Added Dose 1 arthralgia, myalgia, and fatigue AE because they all extended beyond 7 days. Dose 2 had none extending beyond 7 days' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 19:31:44
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 14:20:02
User opened query 'Per review, while subject was in hospital admission, it was also stated that subject had Leukocytosis (likely reactive). Please update and include in database.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:56:52
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 138, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:56:58

US3522666

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:03:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Safety Follow Up Diary Day 138, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Per staff communication (see source document) AEs reported related to cardiac condition, not covid-19' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	07 Apr 2021 21:01:41
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 138, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	27 Mar 2021 06:14:21
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 19:22:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	02 Feb 2021 20:15:02
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	20 Oct 2020 14:15:14

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:47:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User coded data point as SOC: Psychiatric disorders, HLT: Disturbances in thinking and perception, HLT: Hallucinations (excl sleep-related), PT: Hallucination, LLT: Hallucination - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 14:19:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 14:19:35
Data point term sent to Coder	System	20 Oct 2020 14:17:57
User entered 'Hallucination'	(b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:47:56
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:47:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:47:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:48:00
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:48:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '03:00'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 03:00'	System	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:48:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:48:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:48:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '04:00'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 04:00'	System	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:50:58
Query 'Grade not indicated in source. Please clarify. ' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 13:50:57
User opened query 'Grade not indicated in source. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 13:48:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:48:23
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:51:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'See source doc.'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 14:17:00

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:52:18
User closed query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 07:46:43
Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'is a continuation of the eduary entry that started right after second injection, was viewed as a solicited adverse reaction not an illness symptom' (Site from DM).	Sharon Mathys (b) (4)	17 Mar 2021 19:55:52
User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:23:12
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:58:36

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable. Otherwise, clarify.' answered with 'updated to correct timeline per source data to reflect continuing of AE past Ediary entries ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:18:31
User opened query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4. Please review and update to delete/remove AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 02:43:35
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:59:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:59:32
Data point term sent to Coder	System	20 Oct 2020 14:20:02
User entered 'Nausea remaining after 7 days after 2nd injection'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:52:27
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:52:34
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:32:43
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' answered with 'updated' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:46:21
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:46:12
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 04:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '20 Oct 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Dec 2020 17:16:47
User entered '12 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:38
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	28 Dec 2020 17:17:13
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 17:17:13
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Dec 2020 17:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Oct 2020 14:21:07
User entered '17:00' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:21:07
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Oct 2020 14:19:33
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 17:17:13
User entered '20 Oct 2020 17:00'	System	28 Dec 2020 17:16:47
User entered '12 Oct 2020 17:00'	System	20 Oct 2020 14:21:07
User entered empty.	System	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:43
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 12:56:18
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:17:28
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	28 Dec 2020 17:16:47
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 02:43:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:21:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 14:21:07
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	20 Oct 2020 14:21:07
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:19:33
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:45
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '26 Oct 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Dec 2020 17:16:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:53:51
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Oct 2020 14:21:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 14:21:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	20 Oct 2020 14:21:07
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 14:19:33
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:16:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

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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 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:54:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'See source doc'	(b) (4), (b) (6)	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 14:19:33

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User closed query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).</td <td>(b) (4), (b) (6)</td> <td>19 Mar 2021 07:46:55</td>	(b) (4), (b) (6)	19 Mar 2021 07:46:55
Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'Participant did nto want to do an illness visit and based on doctor visit and history it was viewed as unrelated. Logging deviation' (Site from DM).</td <td>Sharon Mathys (b) (4)</td> <td>17 Mar 2021 19:59:42</td>	Sharon Mathys (b) (4)	17 Mar 2021 19:59:42
User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).</td <td>(b) (4), (b) (6)</td> <td>17 Mar 2021 09:22:50</td>	(b) (4), (b) (6)	17 Mar 2021 09:22:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:33:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:33:49
Data point term sent to Coder	System	10 Feb 2021 16:33:15
User entered 'Fatigue'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 21:11:29
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 21:11:29
User signature succeeded.	(b) (4)	
	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 21:11:29
	(b) (4)	
User entered '19 Feb 2021' reason for change: New Information	Yaman Ahmed (b) (4)	09 Mar 2021 21:11:29
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 16:32:46

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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)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:32:46

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
Signature has been broken.	Yaman Ahmed (b) (4)	09 Mar 2021 21:11:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Yaman Ahmed (b) (4)	09 Mar 2021 21:11:29
New Information	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Participant started experiencing fatigue 06-FEB-2021 which is ongoing as of 10-FEB-2021 but starting to resolve.'	(b) (4), (b) (6)	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:32:46

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:36:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:36:49
Data point term sent to Coder	System	10 Feb 2021 16:36:19
User entered 'nausea'	(b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '07 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:47
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Participant states nausea started 07-FEB-2021 AND RESOLVED 08-FEB-2021. SEE SOURCE NOTE FOR DETAILS.'	(b) (4), (b) (6)	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:35:37

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:38:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:38:49
Data point term sent to Coder	System	10 Feb 2021 16:38:21
User entered 'VOMITING'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Feb 2021 16:38:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 16:38:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 16:38:08
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 16:38:00
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'See source note for details'	(b) (4), (b) (6)	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:38:08

US3522666

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:38:00

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:40:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:40:55
Data point term sent to Coder	System	10 Feb 2021 16:40:31
User entered 'diarrhea'	(b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, HE TOOK PEPTO BISMOL "2 TABLESPOONS" 3 TIMES THROUGHOUT THE DAY. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:55:08
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, HE TOOK PEPTO BISMOL "2 TABLESPOONS" 3 TIMES THROUGHOUT THE DAY. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:18:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, HE TOOK PEPTO BISMOL "2 TABLESPOONS" 3 TIMES THROUGHOUT THE DAY. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 02:31:25
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 19:22:06
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Participant developed diarrhea on 08-FEB-2021 for which he took Pepto bismol "2 tablespoons" 3 times throughout the day. He states that by 09-FEB-2021 mid morning, the diarrhea had resolved.'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:40:27

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:42:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 16:42:57
Data point term sent to Coder	System	10 Feb 2021 16:42:33
User entered 'body aches'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 18:51:09
	(b) (4)	
User entered '08 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	09 Mar 2021 18:51:09
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered '08 Jan 2021'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 18:51:09
	(b) (4)	
User entered '10 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	09 Mar 2021 18:51:09
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
	(b) (4)	
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 16:43:05
User entered '09 Jan 2021'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Feb 2021 16:42:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 16:42:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 16:42:29
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 16:42:23
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 16:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:22:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:55:57
User closed query 'Per DM CLR: Narrative = BODY ACHES STARTED 08-FEB-2021 AND RESOLVED 10-FEB-2021. Please review and confirm if the start/end dates should be reconciled with the recorded start/end date of this AE. Review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 03:48:02
Query 'Per DM CLR: Narrative = BODY ACHES STARTED 08-FEB-2021 AND RESOLVED 10-FEB-2021. Please review and confirm if the start/end dates should be reconciled with the recorded start/end date of this AE. Review and update AE eCRF as appropriate. ' answered with 'entry error; updated' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 18:51:25
User opened query 'Per DM CLR: Narrative = BODY ACHES STARTED 08-FEB-2021 AND RESOLVED 10-FEB-2021. Please review and confirm if the start/end dates should be reconciled with the recorded start/end date of this AE. Review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 02:31:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 19:22:06
User entered 'BODY ACHES STARTED 08-FEB-2021 AND RESOLVED 10-FEB-2021. SEE SOURCE NOTE FOR DETAILS.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 16:43:05
User entered 'Body aches started 08-FEB-2021 and resolved 09-FEB-2021. see source note for details.'	(b) (4), (b) (6)	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:42:29

US3522666

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 16:42:23

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:45:17
User closed query 'Please advise what was diagnosed for this positive stress test (eg coronary artery disease etc). The outcome/result cannot be the event. If CAD as outlined in the baseline is worsening please update description and provide source for grading showing worsening from baseline. Thank you' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:46:24
Query 'Please advise what was diagnosed for this positive stress test (eg coronary artery disease etc). The outcome/result cannot be the event. If CAD as outlined in the baseline is worsening please update description and provide source for grading showing worsening from baseline. Thank you' answered with 'see next line' (Site from CRA).	Alandra White (b) (4) (b) (4)	29 Apr 2021 18:02:21
User opened query 'Please advise what was diagnosed for this positive stress test (eg coronary artery disease etc). The outcome/result cannot be the event. If CAD as outlined in the baseline is worsening please update description and provide source for grading showing worsening from baseline. Thank you' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:08:57
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:01:54
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac function diagnostic procedures, PT: Cardiac stress test abnormal, LLT: Cardiac stress test abnormal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:19:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:19:42
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:32:07
Data point term sent to Coder	System	09 Mar 2021 21:14:09
User entered 'positive cardiac stress test'	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 21:13:58

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:45:19
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:01:58
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:45:23
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:02:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:45:25
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:04:23
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:45:27
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:04:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '8 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:45:29
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:48
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:04:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 21:13:58

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:45:31
Signature has been broken.	Alandra White (b) (4)	29 Apr 2021 18:11:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	29 Apr 2021 18:11:02
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 14:05:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:04:33
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Yes (Y)'	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:04
Signature has been broken.	(b) (4)	
	Alandra White (b) (4)	29 Apr 2021 18:11:02
	(b) (4)	
User entered '8 Feb 2021' reason for change: Data Entry Error	Alandra White (b) (4)	29 Apr 2021 18:11:02
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:51
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:04:34
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:06
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:05:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:04:36
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 21:13:58

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:16
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:24
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

US3522666

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:28
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:33
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:37
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:39
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:41
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:43
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:45
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:48
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:51
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'I'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:57
Signature has been broken.	(b) (4)	
	Alandra White (b) (4)	29 Apr 2021 18:11:02
	(b) (4)	
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Alandra White (b) (4)	29 Apr 2021 18:11:02
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:46:59
Signature has been broken.	(b) (4)	
	Alandra White (b) (4)	29 Apr 2021 18:11:02
	(b) (4)	
User entered 'Worsening of coronary artery disease'	Alandra White (b) (4)	29 Apr 2021 18:11:02
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:47:01
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Had chemical cardiac stress test a month ago which was abnormal so is scheduled for cardiac catheterization on 12 Mar 2021'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 21:13:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:57:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:55:52
Un-reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:55:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:55:34
Un-reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 12:55:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:37:05
User entered 'USA-US131-2021-mRNA-1273-P301000013'	System	25 Mar 2021 16:36:58
User entered 'New'	(b) (4), (b) (6)	25 Mar 2021 16:36:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As subject has a prior history of coronary artery disease, please consider updating event term to worsening of coronary artery disease.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 14:57:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:39
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 aggravated - version MedDRA\23.0.	Coder Import (b) (4)	26 Apr 2021 18:00:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	26 Apr 2021 18:00:57
Data point term sent to Coder	System	26 Apr 2021 18:00:11
Query 'PV Query: As subject has a prior history of coronary artery disease, please consider updating event term to worsening of coronary artery disease.' answered with 'updated to "WORSENING OF CORONARY ARTERY DISEASE"' (Site from Safety).	Alandra White (b) (4)	26 Apr 2021 18:00:05
DataPoint Un-verified.	(b) (4)	
Coding entries removed.	Alandra White (b) (4)	26 Apr 2021 17:59:46
User entered 'Worsening of CORONARY ARTERY DISEASE' reason for change: Data Entry Error	(b) (4)	26 Apr 2021 17:59:46
User opened query 'PV Query: As subject has a prior history of coronary artery disease, please consider updating event term to worsening of coronary artery disease.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 22:59:48
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:57:33
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 17:09:16
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.	Coder Import (b) (4)	06 Apr 2021 18:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	06 Apr 2021 18:54:40

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Apr 2021 18:53:44
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.	Coder Import (b) (4)	06 Apr 2021 18:53:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 18:53:21
Query 'For coding purposes, S/P CABG X3 is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' canceled (Site from System).	Coder Import (b) (4)	06 Apr 2021 18:53:19
User closed query 'For coding purposes, S/P CABG X3 is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	System	06 Apr 2021 18:53:17
Query 'For coding purposes, S/P CABG X3 is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 18:53:17
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 18:53:11
Data point term sent to Coder	System	06 Apr 2021 18:52:40
User entered 'Coronary Artery Disease' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 18:52:29
User opened query 'For coding purposes, S/P CABG X3 is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4)	05 Apr 2021 17:29:20
	(b) (4)	
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:57:19
Data point term sent to Coder	System	24 Mar 2021 20:50:23

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 's/p CABG x3'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:57:36
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:57:37
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:57:39
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:57:40
User entered '16 Mar 2021'	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:57:59
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:36:36
User closed query 'Per source review, it appears that the seriousness of this event has reduced. Please review and update. Create a new entry for lower grade of CAD except it has reverted to baseline grade. Thank you' (Site from CRA).	(b) (4), (b) (6)	03 May 2021 20:36:32
Query 'Per source review, it appears that the seriousness of this event has reduced. Please review and update. Create a new entry for lower grade of CAD except it has reverted to baseline grade. Thank you' answered with 'considered resolved after admission per PI' (Site from CRA).	Alandra White (b) (4)	03 May 2021 19:39:14
User entered 'No (N)' reason for change: Data Entry Error	Alandra White (b) (4)	03 May 2021 19:38:44
User opened query 'Per source review, it appears that the seriousness of this event has reduced. Please review and update. Create a new entry for lower grade of CAD except it has reverted to baseline grade. Thank you' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:59:34
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:36:42
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'considered resolved after admission per PI ' (Site from Safety).	Alandra White (b) (4)	03 May 2021 19:39:31
User entered '26 Mar 2021' reason for change: Data Entry Error	(b) (4)	03 May 2021 19:38:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:07
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:57:08
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:03:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:11
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 20:49:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:11:55
User entered 'Grade 4 (Grade 4)'	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:17
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Mar 2021 20:50:05
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Mar 2021 20:49:45
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:39
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:41
User entered '1' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 20:50:05
User entered '0'	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:43
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		29 Mar 2021 18:42:00
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		29 Mar 2021 18:42:00
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		24 Mar 2021 20:50:38
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		24 Mar 2021 20:50:38
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	24 Mar 2021 20:50:38
User entered '1' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	24 Mar 2021 20:50:38
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) System	24 Mar 2021 20:49:45
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:45
User entered '12 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:46
User entered '26 Mar 2021' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Mar 2021 18:42:00
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	25 Mar 2021 17:59:01
User entered 'No (N)'	(b) (4)	
	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:26
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).		29 Mar 2021 19:02:45
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		29 Mar 2021 19:02:45
User entered '1' reason for change: New Information Sharon Mathys	(b) (4)	29 Mar 2021 19:02:45
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4) System	25 Mar 2021 17:59:01
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:28
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:30
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:31
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:33
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:35
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:37
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:48
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:36:51
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 Conmeds ' (Site from Safety). User entered '1' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	03 May 2021 19:40:15
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). User entered '0'	(b) (4) (b) (4), (b) (6) Yaman Ahmed (b) (4) (b) (4)	29 Apr 2021 18:23:19 02 Apr 2021 22:57:53 24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:00:53
User entered 'I'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:36:56
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'considered resolved to baseline post CABG admission per PI ' (Site from Safety).	Alandra White (b) (4) (b) (4)	03 May 2021 19:40:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	03 May 2021 19:38:44
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)	02 Apr 2021 22:57:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:37:00
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:03
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
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)	29 Apr 2021 22:39:05
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 'No covid-19 testing could be found in EHR review ' (Site from Safety).	Alandra White (b) (4) (b) (4)	29 Apr 2021 18:38:38
User closed query 'PV Query: Please provide date for positive stress test and cardiac catheterization. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 18:22:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:10
Query 'PV Query: Please provide date for positive stress test and cardiac catheterization. If unknown, please indicate so. ' answered with '12-MAR-2021 cardiac cath, source epic in care everywhere under surgical history. Unknown stress test date, marked as 08-FEB-2021 in conproc' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:24:18
User entered 'UNDERWENT EVALUATION FOR SYMPTOMS OF EXERTIONAL ANGINA (POSITIVE STRESS STRESS 08-feb-2021). CARDIAC CATHERIZATION 12-MAR-2021 DEMONSTRATED MULTI-VESSEL CORONARY ARTERY DISEASE AND UNDERWENT THE GRAFTING FOR THAT ON 16 MAR 2021...23 MAR 2021 CALL (DOCUMENTED SYMPTOMS OF SOB, DIFFICULTY BREATHING, FATIGUE, BODY ACHES, HEADACHE AND NAUSEA IN E-DIARY), HE SAYS HE'S DOING BETTER AND POSSIBLY WILL BE PLACED IN OUTPATIENT REHAB ON 24 MAR 2021 WHERE HE WILL STAY 4-5 DAYS' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:17:51

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
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)	09 Apr 2021 13:37:33
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 'documents have been sent' (Site from Safety).	Sharon Mathys (b) (4)	08 Apr 2021 18:59:42
User opened query 'PV Query: Please provide date for positive stress test and cardiac catheterization. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:57:41
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)	02 Apr 2021 22:56:50
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)	02 Apr 2021 22:56:40

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'UNDERWENT EVALUATION FOR SYMPTOMS OF EXERTIONAL ANGINA (POSITIVE STRESS STRESS). CARDIAC CATHERIZATION DEMONSTRATED MULTI-VESSEL CORONARY ARTERY DISEASE AND UNDERWENT THE GRAFTING FOR THAT ON 16 Mar 2021...23 MAR 2021 CALL (DOCUMENTED SYMPTOMS OF SOB, DIFFICULTY BREATHING, FATIGUE, BODY ACHES, HEADACHE AND NAUSEA IN E-DIARY), HE SAYS HE'S DOING BETTER AND POSSIBLY WILL BE PLACED IN OUTPATIENT REHAB ON 24 MAR 2021 WHERE HE WILL STAY 4-5 DAYS' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	25 Mar 2021 17:55:42
User entered 'UNDERWENT EVALUATION FOR SYMPTOMS OF EXERTIONAL ANGINA (POSITIVE STRESS STRESS). CARDIAC CATHERIZATION DEMONSTRATED MULTI-VESSEL CORONARY ARTERY DISEASE AND UNDERWENT THE GRAFTING FOR THAT on 23 Mar 2021 call (documented symptoms of SOB, difficulty breathing, fatigue, body aches, headache and nausea in e-diary), he says he's doing better and possibly will be placed in outpatient rehab on 24 Mar 2021 where he will stay 4-5 days' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	24 Mar 2021 20:55:14
User entered 'underwent evaluation for symptoms of exertional angina (positive stress stress). Cardiac catheterization demonstrated multi-vessel coronary artery disease and underwent the grafting for that'	Yaman Ahmed (b) (4)	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 17:59:01
User entered '0'	System	24 Mar 2021 20:49:45

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:35:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:15:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:15:17
Data point term sent to Coder	System	25 Mar 2021 17:50:57
User entered 'Pleural effusion (left)'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:35:37
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:35:39
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:35:41
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please review as source states date noted is 22MAR2021 for Pleural effusion.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:28:32
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:28:29
Query 'Please review as source states date noted is 22MAR2021 for Pleural effusion.' answered with 'updated per source ' (Site from CRA).	Alandra White (b) (4)	29 Apr 2021 18:45:57
User entered '22 Mar 2021' reason for change: Data Entry Error	(b) (4)	29 Apr 2021 18:45:46
User opened query 'Please review as source states date noted is 22MAR2021 for Pleural effusion.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:35:31
Query 'Please review as start date is 22MAR2021 in source. ' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:33:17
User opened query 'Please review as start date is 22MAR2021 in source. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:21:22
User entered '19 Mar 2021'	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:28:34
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:28:37
User entered 'No (N)' reason for change: Data Entry Error	Alandra White (b) (4)	29 Apr 2021 18:58:50
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:28:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 18:59:14
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	29 Apr 2021 18:59:14
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 18:59:02
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 18:59:02
User entered '24 Mar 2021' reason for change: Data Entry Error	Alandra White (b) (4)	29 Apr 2021 18:59:02
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 18:58:50
User entered empty.	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:28:41
User entered empty.	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:28:42
DataPoint Un-verified.	Alandra White (b) (4)	29 Apr 2021 18:58:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
reason for change: Data Entry Error	Alandra White (b) (4)	29 Apr 2021 18:58:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 14:36:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:00
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:03
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:05
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:19
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:21
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:23
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:25
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:27
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:28
User entered '0'	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:30
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:31
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:33
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:35
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:37
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:39
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 12:33:11
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	29 Apr 2021 18:59:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Alandra White (b) (4)	29 Apr 2021 18:59:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 14:40:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58
	(b) (4)	

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:45
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:40:52
User entered 'POST CABG PLEURAL EFFUSION, THORACENTESIS PERFORMED ON 22 MAR 2021 (730 CC REMOVED). 24 MAR 2021 CHEST X-RAY SHOWS INTERVAL DECREASE IN LEFT EFFUSION' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	25 Mar 2021 18:06:15
User entered 'POST CABG PLEURAL EFFUSION, THORACENTESIS PERFORMED ON 22 MAR 2021 (730 CC REMOVED). 23 Mar 2021 chest x-ray shows interval decrease in left effusion' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	25 Mar 2021 18:05:01
User entered 'post CABG pleural effusion, thoracentesis performed on 22 Mar 2021 (730 cc removed)'	Yaman Ahmed (b) (4)	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 17:49:58

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 13:54:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Apr 2021 13:54:14
Data point term sent to Coder	System	21 Apr 2021 13:49:52
Coding entries removed.	Sharon Mathys (b) (4)	21 Apr 2021 13:49:18
User entered 'FATIGUe' reason for change: Per Query Resolution	(b) (4)	
User entered 'FATIGUe' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	21 Apr 2021 13:49:18
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue aggravated - version MedDRA\\23.0.	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 21:45:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	20 Apr 2021 21:45:42
Data point term sent to Coder	System	20 Apr 2021 19:19:59
User entered 'Fatigue-mild'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '17 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 19:19:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 19:19:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 19:19:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 19:19:46
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '22 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'Related (RELATED)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'None (NONE)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 19:19:46

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:54:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:54:47
Data point term sent to Coder	System	20 Apr 2021 19:24:05
User entered 'myalgia- mild'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '16 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '18 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'Related (RELATED)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'None (NONE)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:59:12
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 19:23:07

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:35:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:35:47
Data point term sent to Coder	System	20 Apr 2021 19:25:06
User entered 'Arthralgia-mild'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:57:13
User entered '16 Sep 2020' reason for change: Data Entry Error	Alandra White (b) (4)	03 May 2021 19:47:24
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	03 May 2021 19:46:57
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	03 May 2021 19:46:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '16 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 19:47:24
User opened query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 19:46:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '22 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 19:47:24
User opened query 'Data is required. Please provide.' (Site from System).	System	03 May 2021 19:46:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 19:25:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 19:25:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 19:25:15
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 19:24:39
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'Related (RELATED)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'None (NONE)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:58:00
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 19:25:15

US3522666

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 19:24:39

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Electrolyte imbalance NEC, PT: Electrolyte imbalance, LLT: Electrolyte disturbance - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 22:34:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 22:34:26
Data point term sent to Coder	System	03 May 2021 22:33:11
User entered 'Electrolyte disturbance'	(b) (4), (b) (6) (b) (4)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant found to have low then high potassium levels, was treated with electrolytes to balance.'	(b) (4), (b) (6)	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 22:32:53

US3522666

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:03:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 22:32:53

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:51:45
User closed query 'Please review source notes for admission and report all of the "facility administered medications" in the database (e.g. Lidocaine, tramadol etc).' (Site from CRA).	(b) (4), (b) (6)	03 May 2021 23:54:21
User closed query 'Per review of medications at discharge, subject was scheduled to start some medications. However, some have been documented since they were already active medications at baseline. However, the following have not been entered: Metformin 500MG and Aspirin 81MG. Please review and add appropriately.' (Site from CRA).	(b) (4), (b) (6)	03 May 2021 23:54:17
Query 'Please review source notes for admission and report all of the "facility administered medications" in the database (e.g. Lidocaine, tramadol etc).' answered with 'added' (Site from CRA).	(b) (4), (b) (6)	03 May 2021 22:33:49
Query 'Per review of medications at discharge, subject was scheduled to start some medications. However, some have been documented since they were already active medications at baseline. However, the following have not been entered: Metformin 500MG and Aspirin 81MG. Please review and add appropriately.' answered with 'They have been added' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:38:01
User opened query 'Please review source notes for admission and report all of the "facility administered medications" in the database (e.g. Lidocaine, tramadol etc).' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:38:19
User opened query 'Per review of medications at discharge, subject was scheduled to start some medications. However, some have been documented since they were already active medications at baseline. However, the following have not been entered: Metformin 500MG and Aspirin 81MG. Please review and add appropriately.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:22:00
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 19:22:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:03:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site and Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:37:08
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2 and 4 Pain at Injection Site, Day 3, 4 and 5 Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:37:02
Query 'Per DM CLR: Per Diary Dose 1 Day 2 and 4 Pain at Injection Site, Day 3, 4 and 5 Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Participant took 200 mg motrin for arm pain on 13-SEP-2021. Will clarify it was injection site pain. Day 3 4 and 5 headache interference with activity. No medication taken. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 15:54:44

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:03:14

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site and Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'participant took 650mg Tylenol on OCT 13th for body aches and headache. Day 1 pain at inj site and headache was some interference with activity only. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 15:52:18
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site and Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 09:10:16
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2 and 4 Pain at Injection Site, Day 3, 4 and 5 Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 09:10:08
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:06:32

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 18:47:06
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 Oct 2020 18:47:06
Data point term sent to Coder	System	08 Oct 2020 13:35:18
Coding entries removed.	(b) (4), (b) (6)	08 Oct 2020 13:34:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:08:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:08:35
Data point term sent to Coder	System	11 Sep 2020 17:07:48
User entered 'Eliquis'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:50:56
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:54:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:53:53
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:18:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered 'A fib' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 13:34:26
User entered 'Blood thinner'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered '5'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:38
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '2'	System	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	11 Sep 2020 17:07:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:09:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:09:37
Data point term sent to Coder	System	11 Sep 2020 17:08:49
User entered 'lipitor'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'hyperlipidemia'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered '10'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:22:39
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
DataPoint Un-verified.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 22:02:48
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 22:02:48
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 22:02:48
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:22:56
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered '6 Apr 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Yaman Ahmed (b) (4)	08 Apr 2021 22:04:07
	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 22:02:48
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 22:02:48
User entered '7 Apr 2021' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	11 Sep 2020 17:07:58

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:09:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:09:38
Data point term sent to Coder	System	11 Sep 2020 17:08:50
User entered 'lexapro'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered 'depression'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered '10'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:08:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:08:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:08:51
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:08:45
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	11 Sep 2020 17:08:45

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE, PRODUCTSYNONYM: PROSCAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:10:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:10:39
Data point term sent to Coder	System	11 Sep 2020 17:09:54
User entered 'Proscar'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'BPH'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered '5'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:44
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	11 Sep 2020 17:09:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:11:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:11:46
Data point term sent to Coder	System	11 Sep 2020 17:10:58
User entered 'Insulin'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'diabetes'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
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)	12 Oct 2020 11:29:04
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 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:54:48
User entered 'Unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:54:41
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)	08 Oct 2020 14:20:44
User entered 'Ranges'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'units'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:47
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	11 Sep 2020 17:10:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
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) (b) (4)	11 Sep 2020 17:12:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:12:39
Data point term sent to Coder	System	11 Sep 2020 17:12:01
User entered 'Flomax'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'BPH'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
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)	12 Oct 2020 11:29:18
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 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:55:30
User entered '0.4' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:55:24
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)	08 Oct 2020 14:19:51
User entered '.5'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	11 Sep 2020 17:11:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:29:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	11 Feb 2021 13:29:52
Data point term sent to Coder	System	10 Feb 2021 15:56:10
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 15:55:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:55
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, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:46:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	25 Sep 2020 17:46:51
Data point term sent to Coder	System	25 Sep 2020 17:46:14
User entered 'Motrin'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:24:48
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 15:55:09
User entered 'pain at site of injection' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 15:55:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered 'arm pain'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered '200'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered '13 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered '13 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AT SITE OF INJECTIONin eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 03:56:31
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AT SITE OF INJECTIONin eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' answered with 'medication for 13 Sept pain at injection site is valid according to him as he did have the pain continuously, so it must have been in error when he didn't check it off on Day 3 and put in "none" but it was present ' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 21:17:45
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AT SITE OF INJECTIONin eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 01:39:53
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:15:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User entered empty.	System	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User entered empty.	System	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:32
User entered empty.	System	25 Sep 2020 17:45:30

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:59:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:59:41
Data point term sent to Coder	System	08 Oct 2020 19:07:30
User entered 'Lisinopril'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'hypertension'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered '10'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'l'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:15:57
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	08 Oct 2020 19:06:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Oct 2020 14:26:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:26:39
Data point term sent to Coder	System	20 Oct 2020 14:25:17
User entered 'Tylenol'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
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, BODY ACHES are 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 and BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 08:11:45
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE, BODY ACHES are 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 and BODY ACHES did not meet the AE reporting criteria.' answered with 'does not meet AE requirements- normal side effect of vaccine and lasted one day. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 16:15:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[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, BODY ACHES are 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 and BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:24:04
User entered 'Headache, body aches'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '650' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:50:42
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 08:11:48
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 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 16:17:32
User entered '325' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:17:25
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)	13 Jan 2021 19:21:49
User entered '800'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 15:50:42
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:17:25
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:25:31
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
User entered empty.	System	10 Feb 2021 15:50:42
User entered '2'	System	29 Jan 2021 16:17:25
User entered empty.	System	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
User entered empty.	System	10 Feb 2021 15:50:42
User entered '1'	System	29 Jan 2021 16:17:25
User entered empty.	System	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:29
User entered empty.	System	10 Feb 2021 15:50:42
User entered '804 (804)'	System	29 Jan 2021 16:17:25
User entered empty.	System	20 Oct 2020 14:24:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 16:18:39
Data point term sent to Coder	System	20 Apr 2021 16:17:04
User entered 'Aspirin'	(b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'cardio protective'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '81'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:06:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	20 Apr 2021 16:16:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE, PRODUCTSYNONYM: PEPTO BISMOL [BISMUTH SUBSALICYLATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 19:17:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 19:17:39
Data point term sent to Coder	System	09 Mar 2021 19:17:00
User entered 'Pepto Bismol'	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'diarrhea'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '525'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'three times daily (TID)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 19:16:40
	(b) (4)	

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '8 Feb 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '8 Feb 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:06
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
User entered '3'	System	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
User entered '1'	System	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:37
User entered '804 (804)'	System	09 Mar 2021 19:16:40

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 22:04:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:04:59
Data point term sent to Coder	System	08 Apr 2021 22:04:20
User entered 'Lipitor'	Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'hyperlipidemia'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered '40'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 22:03:42
	(b) (4)	

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'once daily (QD)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 22:03:42
	(b) (4)	

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered '7 Apr 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:26:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	08 Apr 2021 22:03:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 20:06:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:06:46
Data point term sent to Coder	System	20 Apr 2021 17:02:17
Data point term sent to Coder	System	20 Apr 2021 17:01:16
Data point term sent to Coder	System	20 Apr 2021 17:00:15
User entered 'furosemide (LASIX)'	(b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'pleural effusion' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:01:54
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 17:00:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 17:00:20
User entered 'Diuretic related to cardiac issues' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 17:00:20
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 17:00:07
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '40'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
User entered '2'	System	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
User entered '1'	System	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:23
User entered '804 (804)'	System	20 Apr 2021 17:00:07

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:26:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:26:32
Data point term sent to Coder User entered 'Tylenol'	System (b) (4), (b) (6)	20 Apr 2021 16:26:13 20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Surgery pain'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '500'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:40
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
User entered '4'	System	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
User entered '1'	System	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:15
User entered '804 (804)'	System	20 Apr 2021 16:25:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:27:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:27:50
Data point term sent to Coder	System	20 Apr 2021 16:27:14
User entered 'Tylenol'	(b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Surgery pain'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '650'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '25 Mar 2021'	(b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:07:48
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
User entered empty.	System	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
User entered empty.	System	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:48
User entered empty.	System	20 Apr 2021 16:26:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Apr 2021 18:59:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Apr 2021 18:59:46
Data point term sent to Coder	System	20 Apr 2021 16:31:18
User entered 'albumin human 5 % infusion'	(b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Post surgical'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '12.5'	(b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'g (g)'	(b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:08:25
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
User entered empty.	System	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
User entered empty.	System	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:26
User entered empty.	System	20 Apr 2021 16:31:15

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL, PRODUCTSYNONYM: ZYLOPRIM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 18:59:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 18:59:46
Data point term sent to Coder	System	20 Apr 2021 16:41:45
User entered 'allopurinol (ZYLOPRIM)'	(b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'unknown why received two doses'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '300'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:23
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
User entered '1'	System	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
User entered '1'	System	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:33
User entered '804 (804)'	System	20 Apr 2021 16:40:57

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:50
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
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: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 09:28:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 09:28:58
Data point term sent to Coder	System	20 Apr 2021 16:44:49
User entered 'calcium gluconate 1 g in dextrose 5 % 50 mL infusion 1 g, Administer over 30 Minutes, Intravenous, ONCE,'	(b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:52
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:53
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'electrolyte replacement'	(b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:55
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:56
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'g (g)'	(b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:57
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:10:01
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:09:59
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:26
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:29
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:30
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:32
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:34
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:11:36
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
User entered empty.	System	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
User entered empty.	System	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:43
User entered empty.	System	20 Apr 2021 16:43:55

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:07:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:07:35
Data point term sent to Coder	System	20 Apr 2021 16:45:50
User entered 'cefTRIAXone (ROCEPHIN)'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Surgical infections prophylaxis'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '2'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'g (g)'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '18 Mar 2021'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:41
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
User entered '1'	System	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
User entered '1'	System	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:53
User entered '804 (804)'	System	20 Apr 2021 16:45:20

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Apr 2021 16:53:35
Data point term sent to Coder	System	20 Apr 2021 16:53:03
User entered 'Colace'	(b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'constipation prophylaxis'	(b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '100'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Apr 2021 16:57:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 16:57:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 16:57:38
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 16:52:21
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:39
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
User entered '2'	System	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
User entered '1'	System	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:00
User entered '804 (804)'	System	20 Apr 2021 16:52:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE, PRODUCTSYNONYM: ADRENALIN [EPINEPHRINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 10:14:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 10:14:04
Data point term sent to Coder	System	20 Apr 2021 16:55:08
User entered 'EPINEPHrine (ADRENALIN)1 mg in dextrose 5 % 250 mL infusion'	(b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Coronary Artery Disease'	(b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	20 Apr 2021 16:58:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 16:58:04
User entered '0.1-10' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 16:58:04
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 16:54:38
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0.1-10 mcg/min'	(b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:12:28
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
User entered empty.	System	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
User entered empty.	System	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:01
User entered empty.	System	20 Apr 2021 16:54:38

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 11:04:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 11:04:07
Data point term sent to Coder	System	20 Apr 2021 16:56:09
User entered 'Pepcid'	(b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Prevents ulcers'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '20'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'both IV and oral'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:11
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
User entered '1'	System	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
User entered '1'	System	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:03
User entered '804 (804)'	System	20 Apr 2021 16:56:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
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)	20 Apr 2021 20:11:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:11:45
Data point term sent to Coder	System	20 Apr 2021 17:06:24
User entered 'Heparin'	(b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'blood clots prophylaxis/Coronary artery disease'	(b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '400-3000'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'IU (IU)'	(b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'continuous'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:33
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
User entered empty.	System	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
User entered empty.	System	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:02:09
User entered empty.	System	20 Apr 2021 17:05:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
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)	20 Apr 2021 17:08:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 17:08:45
Data point term sent to Coder	System	20 Apr 2021 17:07:35
User entered 'Heparin'	(b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'blood clots prophylaxis'	(b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '5000'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'IU (IU)'	(b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'three times daily (TID)'	(b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:14:37
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:28:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
User entered '3'	System	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
User entered '1'	System	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:01:39
User entered '804 (804)'	System	20 Apr 2021 17:06:59

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:36:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:36:27
Data point term sent to Coder	System	03 May 2021 20:22:14
User entered 'HYDROcodone-acetaminophen (NORCO'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered 'Post surgical pain'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered '5-325'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered '22 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:04
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:22:12

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:36:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:36:27
Data point term sent to Coder	System	03 May 2021 20:25:27
User entered 'HYDROmorphone (DILAUDID'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered 'Post surgical pain'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered '0.5'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered '18 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:12
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:24:23

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
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, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
Data point term sent to Coder	System	03 May 2021 20:26:28
User entered 'insulin glargine (LANTUS'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered '18'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered '24 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered '26 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:15
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 20:26:09

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
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.	Coder Import (b) (4) (b) (4)	03 May 2021 20:27:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:27:16
Data point term sent to Coder	System	03 May 2021 20:26:28
User entered 'metformin'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered 'Diabetes Type 2'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered '500'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered 'twice daily (BID)'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered '18 Jan 2021'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered '0'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:18
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '2'	System	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 20:26:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
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, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
Data point term sent to Coder	System	03 May 2021 20:28:30
User entered 'insulin glargine (LANTUS'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered '25'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered '18 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:20
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 20:27:39

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
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, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
Data point term sent to Coder	System	03 May 2021 20:29:39
User entered 'insulin glargine (LANTUS'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'diabetes'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered '32'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'every morning'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered '13 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered '15 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:25
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:29:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
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, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
Data point term sent to Coder	System	03 May 2021 20:30:41
User entered 'insulin glargine (LANTUS)'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '32'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'Daily at hour of sleep'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '12 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '14 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:30:33

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:35
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)	03 May 2021 20:37:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:37:27
Data point term sent to Coder	System	03 May 2021 20:34:47
User entered 'insulin lispro (HumaLOG) injection'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:57
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:39:00
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:46:59
User entered '2-5'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	03 May 2021 20:38:33
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	03 May 2021 20:34:35
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 May 2021 20:38:33
User entered 'BEFORE MEALS AND AT BEDTIME'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	03 May 2021 20:38:33
User entered 'BEFORE MEALS AND AT BEDTIME' reason for change: Data Entry Error	Sharon Mathys (b) (4)	03 May 2021 20:38:33
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4)	03 May 2021 20:34:35
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered '12 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered '13 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:53:37
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:34:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
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)	03 May 2021 20:38:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:38:28
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:02
Data point term sent to Coder	System	03 May 2021 20:37:52
User entered 'insulin lispro (HumaLOG)'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:47
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 20:38:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 20:38:40
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	03 May 2021 20:38:40
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 20:37:34
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:04
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:06
User entered '2-5'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:08
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:10
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:11
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:13
User entered 'BEFORE MEALS AND AT BEDTIME'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:14
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:18
User entered '22 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:20
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:22
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:24
User entered '24 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:38:26
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:37:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
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)	03 May 2021 20:41:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:41:44
Data point term sent to Coder	System	03 May 2021 20:40:55
User entered 'insulin lispro (HumaLOG)'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered '4'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'with lunch'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered '24 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered '26 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:40:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
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)	03 May 2021 20:50:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:50:27
Data point term sent to Coder	System	03 May 2021 20:50:03
User entered 'insulin lispro (HumaLOG)'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered '4'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'With dinner'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered '23 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered '25 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:55:45
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:49:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
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)	03 May 2021 20:59:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 20:59:27
Data point term sent to Coder	System	03 May 2021 20:58:14
User entered 'insulin lispro (HumaLOG) injection'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered '5'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'THREE TIMES DAILY WITH MEALS'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered empty.	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered '15 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered '0'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered '15 Mar 2021'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:22
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 20:57:35

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
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 HUMAN, PRODUCTSYNONYM: HUMULIN-R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:24:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:24:25
Data point term sent to Coder	System	03 May 2021 21:02:19
User entered 'insulin regular human Humulin R'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered 'Diabetes'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered '10'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered 'IU (IU)'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:25
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:01:22

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:27:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:27:26
Data point term sent to Coder	System	03 May 2021 21:08:25
User entered 'Lidoderm Patch 5%'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'post surgical pain'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'I'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'Patch'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered '24 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered '26 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:28
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:08:14

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: XYLOCAINE [LIDOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:27:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:27:26
Data point term sent to Coder	System	03 May 2021 21:11:27
User entered 'lidocaine (XYLOCAINE) 1 %'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'iv start pain'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered '0.5'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'mL (mL)'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'intradermal'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:31
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:10:46

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 21:14:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 21:14:28
Data point term sent to Coder	System	03 May 2021 21:13:29
User entered 'Lisinopril'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered 'Hypertension'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered '5'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered '13 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered '15 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:52
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:12:43

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:29:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:29:41
Data point term sent to Coder	System	03 May 2021 22:26:53
Data point term sent to Coder	System	03 May 2021 21:15:31
User entered 'Magnesium'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:26:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:26:51
User entered 'electrolyte disturbance' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:26:51
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:14:47
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered 'I'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered 'g (g)'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered '20 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:26:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:26:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:26:51
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:14:47
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered '21 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:53:55
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:14:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE, PRODUCTSYNONYM: MAG OXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:30:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:30:26
Data point term sent to Coder	System	03 May 2021 21:17:34
User entered 'magnesium oxide (MAG-OXIDE'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered 'vitamin'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered '400'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:54:50
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:17:21

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
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)	03 May 2021 22:34:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:34:26
Data point term sent to Coder	System	03 May 2021 22:27:54
Coding entries removed.	(b) (4), (b) (6)	03 May 2021 22:27:19
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)	03 May 2021 21:23:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 21:23:35
Data point term sent to Coder	System	03 May 2021 21:22:37
User entered 'Magnesium Sulfate'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:27:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:27:19
User entered 'electrolyte disturbance' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:27:19
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:22:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered '2'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered 'g (g)'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:09
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:22:04

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:34:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:34:26
Data point term sent to Coder	System	03 May 2021 21:27:40
User entered 'melatonin tablet 6 mg 6 mg, Oral, EVERY NIGHT AT BEDTIME'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'sleep in hospital'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered '6'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'every night at bedtime'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered '23 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered '25 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:12
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:27:13

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 21:34:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 21:34:22
Data point term sent to Coder	System	03 May 2021 21:33:48
User entered 'metoprolol (LOPRESSOR)'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:47:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 21:47:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 21:47:54
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:33:11
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered 'Hypertension'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered '12.5'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User entered '18 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:26
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:47:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 21:47:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 21:47:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:33:11
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '2'	System	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:33:11

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:41:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:41:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:39:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:39:36
Data point term sent to Coder	System	03 May 2021 21:34:48
User entered 'metoprolol (LOPRESSOR) tablet 12.5 mg 12.5 mg, Oral, EVERY 12 HOURS 3/25/21-3/26/21'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered 'hypertension'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered '12.5'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered '25 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered '26 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:27
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '2'	System	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:33:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:41:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:41:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:39:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:39:36
Data point term sent to Coder	System	03 May 2021 21:35:49
User entered 'metoprolol (LOPRESSOR) tablet 25 mg , Oral, EVERY 12 HOURS 3/19/21 for hypertension'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered 'hyeprtension'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered '25'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:35:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 21:35:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 21:35:23
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:35:17
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:34
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '2'	System	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:35:17

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: MUPIROCIN, PRODUCTSYNONYM: BACTROBAN [MUPIROCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:49:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:49:21
Data point term sent to Coder	System	03 May 2021 21:37:50
User entered 'mupirocin (BACTROBAN) 2 %'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered 'pre and post op prophylaxis for infection'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered '0.25'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered 'g (g)'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered '8 doses'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered '15 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:45
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:37:42

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: ANTIVARICOSE THERAPY, ATC: SCLEROSING AGENTS FOR LOCAL INJECTION, PRODUCT: GLUCOSE;GLYCERYL TRINITRATE, PRODUCTSYNONYM: DEXTROSE;NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:51:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:51:21
Data point term sent to Coder	System	03 May 2021 21:45:05
User entered 'nitroglycerin 50 mg in dextrose 5 % 250 mL infusion'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'worsening Coronary artery disease'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered '5-200'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'ug (ug)'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'continuous'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered '13 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered '14 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:51
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:44:47

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE BITARTRATE, PRODUCTSYNONYM: LEVOPHED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:51:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:51:25
Data point term sent to Coder	System	03 May 2021 21:47:08
User entered 'norepinephrine (LEVOPHED)'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'worsening coronary artery disease'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered '0.5-12'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'ug (ug)'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'continuous'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:55:53
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:46:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:52:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:52:21
Data point term sent to Coder	System	03 May 2021 21:50:09
User entered 'polyethylene glycol 3350 (MIRALAX)'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered 'constipation prophylaxis'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered '17'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered 'g (g)'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered '20 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:58:04
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 21:50:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: KLOR-CON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:52:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:52:21
Data point term sent to Coder	System	03 May 2021 22:28:55
Data point term sent to Coder	System	03 May 2021 21:53:11
User entered 'potassium chloride (KLOR-CON) CR table'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:28:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:28:03
User entered 'electrolyte disturbance' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:28:03
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:53:06
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered '40'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'mEq'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'Four doses'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered '21 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:47
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:53:06

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:53:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:53:21
Data point term sent to Coder	System	03 May 2021 22:28:54
Data point term sent to Coder	System	03 May 2021 21:55:13
User entered 'potassium chloride intermittent infusion'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:28:12
User entered 'electrolyte disturbance' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 21:55:10
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered '20'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'mEq'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'every two hours for 3 doses'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 23:59:57
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:55:10

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:54:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:54:26
Data point term sent to Coder	System	03 May 2021 21:58:14
User entered 'propofol (DIPRIVAN)'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'procedural sedation'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered '4.3-85.2'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'ml per hour'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'continuous'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered empty.	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered '0'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered '16 Mar 2021'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:20
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 21:58:01

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:56:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:56:22
Data point term sent to Coder	System	03 May 2021 22:01:28
User entered 'Senna'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered 'constipation prophylaxis'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered '17.2'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered '15 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered '26 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:00:43
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '2'	System	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 22:01:24

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: ACIDIFIERS, PRODUCT: POTASSIUM PHOSPHATE MONOBASIC, PRODUCTSYNONYM: K-PHOS ORIGINAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:53:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:53:21
Data point term sent to Coder	System	03 May 2021 22:28:54
Data point term sent to Coder	System	03 May 2021 22:03:29
User entered 'potassium phosphate (K-PHOS ORIGINAL)'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:28:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:28:23
User entered 'electrolyte disturbance' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:28:23
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:02:36
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered '1000'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered '19 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:32
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:02:36

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
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: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:56:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:56:22
Data point term sent to Coder	System	03 May 2021 22:28:54
Data point term sent to Coder	System	03 May 2021 22:07:30
User entered 'sodium bicarbonate 8.4 % injection'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:28:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:28:32
User entered 'electrolyte disturbance' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:28:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:06:34
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered '25'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered 'mEq'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered '17 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:02:38
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:06:34

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 23:00:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 23:00:21
Data point term sent to Coder	System	03 May 2021 22:19:49
Data point term sent to Coder	System	03 May 2021 22:09:31
User entered 'sulfamethoxazole-trimethoprim double str (BACTRIM DS)'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:19:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:19:01
User entered 'prophylactic treatment of possible uti (culture negative)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:19:01
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:08:51
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered '800-160'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered '22 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:19:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:19:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:19:01
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:08:51
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered '23 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:14
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '2'	System	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '1'	System	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered '804 (804)'	System	03 May 2021 22:08:51

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:11:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 22:11:24
Data point term sent to Coder	System	03 May 2021 22:10:32
User entered 'Tramadol'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered 'post surgical pain'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered '50'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered '24 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered '26 Mar 2021'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
DataPoint Verified.	(b) (4), (b) (6)	04 May 2021 00:03:26
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:09:52

US3522666

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 08:03:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:18:35
User entered empty.	System	03 May 2021 22:09:52

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:03:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:30
User closed query 'Please update Procedures page with Coronary Angiography that occurred on 12Mar2021 at different hospital.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:13:25
Query 'Please update Procedures page with Coronary Angiography that occurred on 12Mar2021 at different hospital.' answered with 'added' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:19:49
User opened query 'Please update Procedures page with Coronary Angiography that occurred on 12Mar2021 at different hospital.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:11:54
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:14:14

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:14
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered '8 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:14:53
	(b) (4)	

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:08
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:14
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'chemical cardiac stress test'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 21:14:53

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:09
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:14
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered 'Medical History (MH)'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:14:53
	(b) (4)	

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:14

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:11
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 13:40:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:14
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:32:07
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 21:14:53
	(b) (4)	

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:39
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered '16 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:34:20

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:39
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'coronary artery bypass grafting x3 (LIMA to LAD, SVG to OM, SVG to PDA)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:34:20

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:39
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'Medical History (MH)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:34:20

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:10
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:39
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	24 Mar 2021 20:34:20
	(b) (4)	

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:54
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered '16 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:35:58

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:54
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'Endoscopic vein harvesting of the left greater saphenous vein'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:35:58

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:54
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'Medical History (MH)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:35:58

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:15
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:54
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:35:58

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:57
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered '16 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:36:20

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:57
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'Excision of left atrial appendage'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:36:20

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:57
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'Medical History (MH)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:36:20

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:52
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:57:57
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered empty.	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:36:20

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:00
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered '16 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:36:50

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:00
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'Open reduction rigid internal sternal fixation (sternalock planting system)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:36:50

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:00
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'Medical History (MH)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 20:36:50

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:12:55
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:58:00
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	24 Mar 2021 20:36:50
	(b) (4)	

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:37
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered '22 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:50:49

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:37
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'THORACENTESIS (LEFT pleural effusion)' reason for change: Data Entry Error	(b) (4)	
User entered 'Thoracentesis (left)'	Yaman Ahmed (b) (4)	25 Mar 2021 17:51:11
	(b) (4)	
	Yaman Ahmed (b) (4)	25 Mar 2021 17:50:49
	(b) (4)	

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:37
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'Adverse Event (AE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	25 Mar 2021 17:50:49

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:37
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	25 Mar 2021 17:50:49
	(b) (4)	

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:51
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:35:35
User entered '12 Mar 2021'	(b) (4), (b) (6)	13 Apr 2021 16:19:34

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:51
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:35:35
User entered 'Coronary Angiography'	(b) (4), (b) (6)	13 Apr 2021 16:19:34

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:51
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:35:35
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Apr 2021 16:19:34

US3522666

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:51
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:35:35
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 16:19:34

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Paul'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered 'Kilgore'	(b) (4), (b) (6)	25 Mar 2021 16:36:58
	System	

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered (b) (6)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered 'Paul'	(b) (4), (b) (6)	25 Mar 2021 16:36:58
	System	

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Kilgore'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)'	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered '25/Mar/2021 16:42'	(b) (4) System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:14

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)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Paul'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Kilgore'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)'	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered '26/Mar/2021 10:28'	(b) (4) System	26 Mar 2021 14:28:18

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:14

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)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 14:28:18

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Paul'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Kilgore'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)'	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered '30/Mar/2021 08:56'	(b) (4) System	30 Mar 2021 12:56:17

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:14

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)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 12:56:17

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Paul'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Kilgore'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered (b) (6) '	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered (b) (6)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered '07/Apr/2021 14:21'	(b) (4) System	07 Apr 2021 18:21:29

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:14

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)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:02:51
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 18:21:29

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Paul'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Kilgore'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)'	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:03:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:48
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:35:35
User entered '13/Apr/2021 11:19'	(b) (4) System	13 Apr 2021 18:19:14

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:03:14

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)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:00:48
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:35:35
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 18:19:14

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Paul'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered 'Kilgore'	(b) (4), (b) (6)	25 Mar 2021 16:36:58
	System	

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)'	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:03:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:22:48
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
User entered '27/Apr/2021 10:59'	(b) (4) System	27 Apr 2021 15:00:03

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:03:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:22:51
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
User entered 'I'	(b) (4), (b) (6)	27 Apr 2021 15:00:03

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:27
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'USA-US131-2021-MRNA-1273-P301000013'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Yes (Y)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

US3522666

Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'No (N)'	System	25 Mar 2021 16:36:58

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:09
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Marcus'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'Paul'	System	25 Mar 2021 16:36:58

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Folder: SAE USA-US131-2021-MRNA-1273-P301000013

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:11
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Zervos'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered 'Kilgore'	(b) (4), (b) (6)	25 Mar 2021 16:36:58
	System	25 Mar 2021 16:36:58

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Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:17
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '2799 West Grand Blvd'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

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Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:15
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered 'Detroit'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6) '	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

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Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:14

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 02:09:06
Query 'Please enter state of site address (i.e. MI)' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 17:24:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
User opened query 'Please enter state of site address (i.e. MI)' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:02:45
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered empty.	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:42:34
User entered 'MI'	System	25 Mar 2021 16:36:58

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Form: Safety Report Form

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Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 22:39:21
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:03:22
User signature succeeded.	Marcus Zervos (b) (4)	28 Apr 2021 20:47:51
Un-reviewed for Safety.	(b) (4)	27 Apr 2021 15:00:03
DataPoint Un-verified.	System	27 Apr 2021 15:00:03
Signature has been broken.	System	27 Apr 2021 15:00:03
User entered '48202'	System	27 Apr 2021 15:00:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
Reviewed for Safety.	(b) (4)	25 Mar 2021 16:42:34
User entered (b) (6)'	(b) (4), (b) (6)	
	System	25 Mar 2021 16:36:58

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Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 14:59:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:47:52
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:27:02
	(b) (4)	
User entered 'US'	System	25 Mar 2021 16:42:51

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Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 22:40:53
User entered '6'	System	27 Apr 2021 15:00:03
User entered '5'	System	13 Apr 2021 18:19:14
User entered '4'	System	07 Apr 2021 18:21:29
User entered '3'	System	30 Mar 2021 12:56:17
User entered '2'	System	26 Mar 2021 14:28:18
User entered '1'	System	25 Mar 2021 16:42:51

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Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (7)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	30 Apr 2021 17:47:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:23:03
User entered '29/Apr/2021 18:40'	System	29 Apr 2021 22:40:53

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Folder: SAE USA-US131-2021-MRNA-1273-P301000013

Form: Safety Report Form (7)

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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.	Marcus Zervos (b) (4)	30 Apr 2021 17:47:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 17:23:05
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 22:40:53