

US3532192 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:12:18

All time stamps listed in this document are displayed in GMT

US3532192

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:14:30

Generated On: 10 Jun 2021 08:12:18

Participant ID

US3532192

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

US3532192

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 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

US3532192

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Date of Birth (MMM yyyy)	(b) (6) 1981
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3532192

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input 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

US3532192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3532192

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Condition	CHRONIC KIDNEY FAILURE
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3532192

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3532192

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Condition	INTERMITTENT NOSEBLEEDS
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3532192

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 11:05:11

Generated On: 10 Jun 2021 08:12:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:22 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:22
Height (<i>xxx.x</i>)	185 cm
Weight (<i>xxx.x</i>)	82 kg
BMI (<i>xxx.x</i>)	23.95909 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)	

US3532192

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3532192

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

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

(b) (6) FACILITY
MANAGEMENT

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) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

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	

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:17:31

Generated On: 10 Jun 2021 08:12:18

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3532192

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:17:31

Generated On: 10 Jun 2021 08:12:18

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145425

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) 12 Feb 2021 20:17:31

Generated On: 10 Jun 2021 08:12:18

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) 12 Feb 2021 20:17:31

Generated On: 10 Jun 2021 08:12:18

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)	31 AUG 2020
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:22
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:17:31

Generated On: 10 Jun 2021 08:12:18

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)	31 AUG 2020
Time of assessment (00:00-23:59)	16:18 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 16:18
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 15:45 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 15:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

15:33 (24 HR)

Collection date and time (derived)

31 AUG 2020 15:33

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Collection date (<i>dd MMM yyyy</i>)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	31 AUG 2020 15:20
Nasopharyngeal Swab 2	No		

US3532192

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

31 AUG 2020 16:22

PC Open Date & Time

31 AUG 2020 16:05

PC Close Date & Time

31 AUG 2020 18:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	01 SEP 2020 05:36
PC Open Date & Time	31 AUG 2020 19:30
PC Close Date & Time	01 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 01:55

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 01:35

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 06:55

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

96.7 °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

05 SEP 2020 07:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

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

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 16:23

PC Open Date & Time

31 AUG 2020 16:05

PC Close Date & Time

31 AUG 2020 18:35

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 05:38

PC Open Date & Time

31 AUG 2020 19:30

PC Close Date & Time

01 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 23:18

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 01:36

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 07:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 22:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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 ☐

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

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 16:24
PC Open Date & Time	31 AUG 2020 16:05
PC Close Date & Time	31 AUG 2020 18:35

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

No ☐

Yes ☒

PC Time stamp	01 SEP 2020 05:39
PC Open Date & Time	31 AUG 2020 19:30
PC Close Date & Time	01 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 23:19
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 01:36
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:45
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 07:04
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

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 ☒

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:06
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

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 ☐

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EAB) (1725)

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US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

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)	6 OCT 2020
Time of assessment (00:00-23:59)	13:51 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 13:51
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 15:30
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3532192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

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) 6 OCT 2020

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

Treatment Date and Time (derived) 6 OCT 2020 15:00

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

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	14:23 (24 HR)
Collection date and time (derived)	6 OCT 2020 14:23

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:17:31

Generated On: 10 Jun 2021 08:12:18

Collection date (dd MMM yyyy)			6 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	6 OCT 2020 13:55
Nasopharyngeal Swab 2	No		

US3532192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

06 OCT 2020 15:37

PC Open Date & Time

06 OCT 2020 15:20

PC Close Date & Time

06 OCT 2020 17:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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 97.4 °F

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

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

PC Time Stamp	07 OCT 2020 01:53
PC Open Date & Time	06 OCT 2020 18:45
PC Close Date & Time	07 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 00:05

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 05:50

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

10 OCT 2020 01:42

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 06:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 07:47

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 22:33

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 15:37

PC Open Date & Time

06 OCT 2020 15:20

PC Close Date & Time

06 OCT 2020 17:50

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

07 OCT 2020 01:53

PC Open Date & Time

06 OCT 2020 18:45

PC Close Date & Time

07 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 00:06

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

09 OCT 2020 05:50

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

10 OCT 2020 01:43

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

11 OCT 2020 05:59

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

12 OCT 2020 07:47

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

12 OCT 2020 22:33

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 15:38
PC Open Date & Time	06 OCT 2020 15:20
PC Close Date & Time	06 OCT 2020 17:50

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 01:55
PC Open Date & Time	06 OCT 2020 18:45
PC Close Date & Time	07 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

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 ☒

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 05:51
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

		Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 01:43	
PC Open Date & Time	09 OCT 2020 12:00	
PC Close Date & Time	10 OCT 2020 11:59	

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

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)

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 05:59
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

101 of 2950

EAB) (1725)

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 07:48
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

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 ☒

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 22:33
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:05:10

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:17:30

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3532192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

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.

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 NOV 2020
Collection time (00:00-23:59)	15:19 (24 HR)
Collection date and time (derived)	11 NOV 2020 15:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:17:57

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

31 OCT 2020 11:20:55

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 01:43:23

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	14 NOV 2020 02:32:27
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 DEC 2020 00:02:38
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	09 DEC 2020 06:33:36
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 04:44:36
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 00:07:15

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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	30 DEC 2020 12:33:22
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 13:31:15

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 JAN 2021 15:44:12
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

20 JAN 2021 00:59:46

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 21:43:15

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

03 FEB 2021 08:18:26

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

10 FEB 2021 00:56:26

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 01:51:49

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 00:01:23

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 00:02:27

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 00:04:42
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 MAR 2021 02:14:34
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 01:46:51

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

31 MAR 2021 01:44:34

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

07 APR 2021 01:58:48

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 13:52:35

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 14:55:21

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 14:41:46

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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°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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

Patient Cloud Open Date & Time	11 AUG 2021 00:01
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Patient Cloud Close Date & Time	15 AUG 2021 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

Patient Cloud Open Date & Time	18 AUG 2021 00:01
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Patient Cloud Close Date & Time	22 AUG 2021 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

Patient Cloud Open Date & Time	25 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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°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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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="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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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°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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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°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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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°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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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°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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	30 OCT 2022 23:59
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US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3532192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:12:18

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		02 MAR 2021 16:40:41

US3532192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:41:57

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:41:57

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 08:42:12

Generated On: 10 Jun 2021 08:12:18

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

Visit date (dd MMM yyyy)	29 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3532192

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

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.

US3532192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	09:58 (24 HR)
Collection date and time (derived)	29 MAR 2021 09:58

US3532192

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:14:33

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 20:22:04

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 20:22:04

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532192

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532192

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532192

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:12:18

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"/>

US3532192

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:12:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3532192

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

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

Visit date (dd MMM yyyy)	25 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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US3532192

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

Date of updated informed consent (*dd MMM yyyy*) 25 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*) 25 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 _____

US3532192

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

10:02 (24 HR)

Collection date and time (derived)

25 JAN 2021 10:02

US3532192

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00 - 23:59)	10:07
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Collection Date and Time (derived)	25 JAN 2021 10:07
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US3532192

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

AEID	
Adverse event	NOSEBLEED
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)	19 OCT 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)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAS HISTORY OF NOSEBLEEDS SINCE 2014. HAS SEEN A DOCTOR FOR THEM IN THE PAST BUT NO KNOWN ETIOLOGY. NOT RELATED TO VACCINE, DUE TO PRIOR HISTORY
Serious Adverse Event Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

AEID	USA-US077-2020-MRNA-1273-P30 1000012
Adverse event	KIDNEY CANCER, RIGHT KIDNEY CLEAR CELL RENAL CELL CARCINOMA, WHO/ISUP GRADE 3
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)	09 NOV 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)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	23 NOV 2020
Admitted to ICU?	
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
	Unknown <input type="radio"/>
Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

NEW DIAGNOSIS OF CANCER.
RIGHT KIDNEY REMOVED.
DIAGNOSED WHEN HE WAS
UNDERGOING WORKUP FOR
KIDNEY TRANSPLANT. NOT
RELATED TO VACCINE. HAD
BASELINE KIDNEY FAILURE

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

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

AEID	USA-US077-2020-MRNA-1273-P30 1000012
Adverse event	RETROPERITONEAL BLEED
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)	18 NOV 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)	20 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	23 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 09:14:33

Generated On: 10 Jun 2021 08:12:18

OCCURRED AFTER SURGERY.
KNOW COMPLICATION FROM
NEPHRECTOMY. NOT RELATED
TO VACCINE OR VACCINE
STUDY PROCEDURES.
SUBJECT HAD BLEEDING POST
RIGHT NEPHRECTOMY.
EXPLORATORY LAP DONE
WHICH FOUND LARGE
RETROPERITONEAL
HEMATOMA. HEMATOMA WAS
EVACUATED AND BLEEDING
AT HILUM SUCCESSFULLY
CLIPPED.

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

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

Yes ☒

No ☐

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication ISOSORBIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN UNK 2014	
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"/>

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 16:09:24

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 10

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23	NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication MULTI-VITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication CHRONIC KIDNEY FAILURE

Dose per administration 1334

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication FUROSEMIDE (LASIX)

Prophylaxis Yes ☐
No ☒

Indication CHRONIC KIDNEY FAILURE

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (10)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication TUMS

Prophylaxis Yes ☐
No ☒

Indication CHRONIC KIDNEY FAILURE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 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)	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 (12)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication BISACODYL

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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 checked="" 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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 975

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication KIDENY CANCER

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication VECURONIUM

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication SUGAMMADEX

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 350

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication SUGAMMADEX

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 30-70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication PROPOFOL
(10MG/ML)

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 50-150

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 16:09:24

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Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 50-150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 700

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		20 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 50

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication MIRALX

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

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 (24)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication NOREPINEPHRINE

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 1.6989

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		20 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication NALOXONE

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 0.04

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 (28)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication MIDAZOLAM
(1MG/ML)

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 16:09:24

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Name of Medication MIDAZOLAM
(1MG/ML)

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		20 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication LACTATE RINGERS

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication INSULIN REGULAR

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 1.6-10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		20 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication HYDROMORPHONE
(2MG/ML)

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 16 Apr 2021 16:09:24

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication HYDROMORPHONE
(2MG/ML)

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication FENTANYL
(50MCG/ML)

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication FENTANYL
(50MCG/ML)

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication EPINEPHRINE-LIDOCAINE
(LIDOCAINE 1% EPI 1:100,000)

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication PLASMA-LYTE

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication PLASMA-LYTE

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 400-1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication DEXTROSE
(50%/50ML)

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

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 (44)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication DESMOPRESSIN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 24

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

TWICE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY CANCER

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication CALCIUM GLUCONATE

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 1000-2000

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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US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)		20 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication DESMOOPRESSIN

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 24

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication RETROPERITONEAL BLEED

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

Name of Medication POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 16 Apr 2021 16:09:24

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Apr 2021 15:49:51

Generated On: 10 Jun 2021 08:12:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 NOV 2020	RIGHT RADICAL NEPHRECTOMY	Adverse Event	
20 NOV 2020	EXPLORATORY LAP: EVACUATION OF HEMATOMA, CLIP PLACEMENT NEAR RENAL HILUM	Adverse Event	
20 NOV 2020	TRANSFUSION OF PLASMA	Adverse Event	
20 NOV 2020	TRANSFUSION OF RBC'S	Adverse Event	

US3532192

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:12:18

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

US3532192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:12:18

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 ☐

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/NOV/2020 08:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/DEC/2020 15:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/DEC/2020 15:37
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

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/DEC/2020 15:40
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

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/FEB/2021 09:31
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

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/MAR/2021 12:34
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

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/MAR/2021 14:19
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

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/DEC/2020 15:41
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

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:14:32

Generated On: 10 Jun 2021 08:12:18

SAEID	USA-US077-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	04/DEC/2020 15:59
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

Audit

US3532192 (Prod: Children's Healthcare of Atlanta)

US3532192

Form: Participant Creation

Generated On: 10 Jun 2021 08:12:18

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'US3532192'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:19:45

US3532192

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 18:48:48

US3532192

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:19:46

US3532192

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Clinic (Clinic)'	Peggy Kettle (b) (4)	31 Aug 2020 18:48:48

US3532192

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered 'SCRN'	System	31 Aug 2020 18:48:48

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered (b) (6) 1981'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:19:47

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '38'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'YEARS'	System	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '38'	System	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Male (M)'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'I'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:12:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 18:49:26

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Aug 2020'	System	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2020'	System	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Amendment 3 (3)'	Peggy Kettle (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 19:09:40

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 18:19:46

US3532192

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:12:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'I'	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:12:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:07:46

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:20:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:20:42
Data point term sent to Coder	System	31 Aug 2020 20:09:14
User entered 'chronic kidney failure'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'un UNK 2014'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Jan 2014'	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2014'	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:08:24

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
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) (4), (b) (6)	15 Oct 2020 07:18:15
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 'was r/t kidney failure and no longer ongoing since dialysis, meds for kidney failure treated the heart failure' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:04:12
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 19:29:01
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:09:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:09:38
Data point term sent to Coder	System	31 Aug 2020 20:09:15
User entered 'congestive heart failure'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'un UNK 2019'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'un UNK 2019'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Jan 2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Jan 2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2019'	System	31 Aug 2020 20:08:53

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 20:11:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 20:11:45
Data point term sent to Coder	System	31 Aug 2020 20:10:15
User entered 'hypertension'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'un UNK 2014' reason for change:	(b) (4)	
Data Entry Error	Peggy Kettle (b) (4)	13 Oct 2020 16:33:17
User entered '31 Aug 2020'	(b) (4)	
	Peggy Kettle (b) (4)	31 Aug 2020 20:09:31
	(b) (4)	

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Jan 2014'	System	13 Oct 2020 16:33:17
User entered 'Aug 2020'	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2014'	System	13 Oct 2020 16:33:17
User entered '2020'	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:09:31

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:09:45
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'MH 1' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:04:47
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:29:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Dialysis, LLT: Dialysis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:11:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:11:45
Data point term sent to Coder	System	31 Aug 2020 20:10:17
User entered 'dialysis'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'un UNK 2018'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:36:27
Query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' answered with 'subject in on dialysis, continuing' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:05:16
User opened query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:29:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Jan 2018'	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2018'	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:09:56

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 00:26:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 00:26:37
Data point term sent to Coder	System	03 Sep 2020 00:25:47
Coding entries removed.	Peggy Kettle (b) (4)	03 Sep 2020 00:25:06
User entered 'HYPOKALEMIA' reason for change: Data Entry Error	Peggy Kettle (b) (4)	03 Sep 2020 00:25:06
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:11:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:11:44
Data point term sent to Coder	System	31 Aug 2020 20:10:18
User entered 'hypocalcemia'	Peggy Kettle (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'un UNK 2018'	Peggy Kettle (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Jan 2018'	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2018'	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	31 Aug 2020 20:10:17

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nosebleed - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 05:12:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 05:12:31
Data point term sent to Coder	System	20 Oct 2020 19:48:02
User entered 'Intermittent Nosebleeds'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'un UNK 2014'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'Jan 2014'	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '2014'	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	20 Oct 2020 19:47:49

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '14:22'	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered '31 Aug 2020 14:22'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '185' cm	(b) (4) Peggy Kettle (b) (4)	31 Aug 2020 19:13:14
DataPoint set to visible.	(b) (4) System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '82' kg reason for change: Data Entry Error	System	31 Aug 2020 19:13:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Peggy Kettle (b) (4)	31 Aug 2020 19:13:25
User entered '82' (non-conformant).	(b) (4)	
DataPoint set to visible.	System	31 Aug 2020 19:13:14
	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14
	(b) (4)	
	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered '23.95909'	System	31 Aug 2020 19:13:25
User entered empty.	System	31 Aug 2020 19:13:14
DataPoint set to visible.	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered 'kg/m2'	System	31 Aug 2020 19:13:25
User entered empty.	System	31 Aug 2020 19:13:14
DataPoint set to visible.	System	31 Aug 2020 19:09:44

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered 'bpm'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered 'breaths/min'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered 'mmHg'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User entered 'mmHg'	System	31 Aug 2020 19:13:14

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11

US3532192

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11

US3532192

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 19:36:21

US3532192

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 19:36:21

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:06:17
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

[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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

[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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:06:43
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	31 Aug 2020 20:06:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:06:17
	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered (b) (6) facility management'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

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 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'I'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:12:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:35:11
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:06:17

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[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 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Clinic (Clinic)'	Peggy Kettle (b) (4)	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'VISIT1'	System	31 Aug 2020 20:02:57

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:14:38

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '145425'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:14:38

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:14:38

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

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 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

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 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 20:03:09

US3532192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:12:18

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 16:09:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:47:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:47:29

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User accepted default value 'Pre-Dose (PREDOSE)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '14:22'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered '31 Aug 2020 14:22'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '97.9' F	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Oral (Oral)'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '63'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'bpm'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '20'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'breaths/min'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '141'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'mmHg'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '82'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'mmHg'	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:12:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered missing code ND - Not Done.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User accepted default value 'Post-Dose (POSTDOSE)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:42:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:42:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:04:01
User entered empty.	System	31 Aug 2020 20:04:01
	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4)	31 Aug 2020 20:42:31
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:04:01
	Peggy Kettle (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '16:18' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	31 Aug 2020 20:42:31
User entered empty.	(b) (4)	
	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered '31 Aug 2020 16:18'	System	31 Aug 2020 20:42:31
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '97.2' F reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 20:42:55
User entered '60' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'bpm'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '16' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'breaths/min'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:39:49
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:21:17
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	31 Aug 2020 20:42:55
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '167' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:04:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'mmHg'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 20:42:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 20:42:55
User entered '99' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:42:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 20:42:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'mmHg'	System	31 Aug 2020 20:42:55
User entered empty.	System	31 Aug 2020 20:04:01

US3532192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:10

US3532192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:10

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

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 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '15:45'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered '31 Aug 2020 15:45'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Left Arm (LEFT ARM)'	Peggy Kettle (b) (4)	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'ONCE'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 20:04:44

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '15:33'	Peggy Kettle (b) (4)	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered '31 Aug 2020 15:33'	System	31 Aug 2020 20:05:01

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:12:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '31 Aug 2020'	Peggy Kettle (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	31 Aug 2020 22:18:49
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	31 Aug 2020 22:18:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 22:18:49
User entered '15:20' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 22:18:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	31 Aug 2020 20:05:23
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	31 Aug 2020 20:05:23
User entered '15:' (non-conformant).	Peggy Kettle (b) (4)	31 Aug 2020 20:05:23
	(b) (4)	

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered '31 Aug 2020 15:20'	System	31 Aug 2020 22:18:49
User entered '31 Aug 2020 15:' (non-conformant).	System	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered empty.	System	31 Aug 2020 20:05:23

US3532192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	31 Aug 2020 20:43:10

US3532192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'I'	System	31 Aug 2020 20:43:10

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b' User entered 'Yes (Y)'	System	31 Aug 2020 20:25:20
	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b' User entered '97.2'	System	31 Aug 2020 20:25:20
	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b' User entered 'No (N)'	System	31 Aug 2020 20:25:20
	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '1dd59f35-d46d-4afc-9156-31e7e682c78b' User entered '31 Aug 2020 16:22'	System	31 Aug 2020 20:25:20
	System	31 Aug 2020 20:25:20

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 16:05'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 18:35'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:35:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855'	System	01 Sep 2020 09:36:18
User entered 'Yes (Y)'	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:35:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855' User entered '98.1'	System	01 Sep 2020 09:36:18
	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:36:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855'	System	01 Sep 2020 09:36:18
User entered 'No (N)'	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:36:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ff7f0a29-733c-41f6-b927-105215afb855'	System	01 Sep 2020 09:36:18
User entered '01 Sep 2020 05:36'	System	01 Sep 2020 09:36:18

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 19:30'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 2'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefaf07ec-d79a-49ff-86eb-e5056bd0f60b' User entered 'Yes (Y)'	System	02 Sep 2020 05:55:35
	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefa07ec-d79a-49ff-86eb-e5056bd0f60b' User entered '97.7'	System	02 Sep 2020 05:55:35
	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefa07ec-d79a-49ff-86eb-e5056bd0f60b' User entered 'No (N)'	System	02 Sep 2020 05:55:35
	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-02T01:55:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fefaf07ec-d79a-49ff-86eb-e5056bd0f60b'	System	02 Sep 2020 05:55:35
User entered '02 Sep 2020 01:55'	System	02 Sep 2020 05:55:35

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 3'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643' User entered 'Yes (Y)'	System	03 Sep 2020 05:35:46
	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643' User entered '97.7'	System	03 Sep 2020 05:35:46
	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:40', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643'	System	03 Sep 2020 05:35:46
User entered 'No (N)'	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '20639c4d-e9f4-4aaa-a3c5-8f16e0c10643' User entered '03 Sep 2020 01:35'	System	03 Sep 2020 05:35:46
	System	03 Sep 2020 05:35:46

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 4'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b' User entered 'Yes (Y)'	System	04 Sep 2020 10:55:39
	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b' User entered '97.4'	System	04 Sep 2020 10:55:39
	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:34', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b' User entered 'No (N)'	System	04 Sep 2020 10:55:39
	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-04T06:55:37', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '777f97fd-c7da-4548-b3f8-483d354a138b' User entered '04 Sep 2020 06:55'	System	04 Sep 2020 10:55:39
	System	04 Sep 2020 10:55:39

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 5'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170' User entered 'Yes (Y)'	System	05 Sep 2020 11:05:40
	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170' User entered '96.7'	System	05 Sep 2020 11:05:40
	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170' User entered 'No (N)'	System	05 Sep 2020 11:05:40
	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:37', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '24ec0331-ed3-46fd-be0e-17a430839170' User entered '05 Sep 2020 07:05'	System	05 Sep 2020 11:05:40
	System	05 Sep 2020 11:05:40

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 6'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7'	System	06 Sep 2020 02:06:22
User entered 'Yes (Y)'	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7' User entered '97.7'	System	06 Sep 2020 02:06:22
	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7'	System	06 Sep 2020 02:06:22
User entered 'No (N)'	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'a8d3491b-52c0-4253-a831-abcbeba25ff7'	System	06 Sep 2020 02:06:22
User entered '05 Sep 2020 22:06'	System	06 Sep 2020 02:06:22

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 7'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:22:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040' User entered 'None (1)'	System	31 Aug 2020 20:26:32
	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040' User entered 'No (N)'	System	31 Aug 2020 20:26:32
	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040' User entered 'No (N)'	System	31 Aug 2020 20:26:32
	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040' User entered 'None (1)'	System	31 Aug 2020 20:26:32
	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5a924a97-cde4-4374-9f10-a9f1525e0040' User entered '31 Aug 2020 16:23'	System	31 Aug 2020 20:26:32
	System	31 Aug 2020 20:26:32

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 16:05'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 18:35'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:37:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b' User entered 'None (1)'	System	01 Sep 2020 09:38:18
	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:37:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b' User entered 'No (N)'	System	01 Sep 2020 09:38:18
	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:37:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b' User entered 'No (N)'	System	01 Sep 2020 09:38:18
	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b' User entered 'None (1)'	System	01 Sep 2020 09:38:18
	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fdf1e3aa-5241-46f4-b134-9753d80e2e9b' User entered '01 Sep 2020 05:38'	System	01 Sep 2020 09:38:18
	System	01 Sep 2020 09:38:18

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 19:30'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 2'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered 'No (N)'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327' User entered 'No (N)'	System	02 Sep 2020 03:18:38
	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327'	System	02 Sep 2020 03:18:38
User entered 'None (1)'	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:34', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0a9dea41-2d94-4758-b8e2-466d350be327' User entered '01 Sep 2020 23:18'	System	02 Sep 2020 03:18:38
	System	02 Sep 2020 03:18:38

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 3'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9'	System	03 Sep 2020 05:36:30
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:16', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9' User entered 'No (N)'	System	03 Sep 2020 05:36:30
	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9' User entered 'No (N)'	System	03 Sep 2020 05:36:30
	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9'	System	03 Sep 2020 05:36:30
User entered 'None (1)'	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b4ea75f3-5bab-45bb-88bd-f85a34467db9' User entered '03 Sep 2020 01:36'	System	03 Sep 2020 05:36:30
	System	03 Sep 2020 05:36:30

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 4'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered 'None (1)'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered 'No (N)'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5' User entered 'No (N)'	System	04 Sep 2020 10:55:21
	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered 'None (1)'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cc147048-95fb-412b-aa9a-4ea82e2d18d5'	System	04 Sep 2020 10:55:21
User entered '03 Sep 2020 20:45'	System	04 Sep 2020 10:55:21

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 5'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8' User entered 'None (1)'	System	05 Sep 2020 11:05:20
	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8' User entered 'No (N)'	System	05 Sep 2020 11:05:20
	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8' User entered 'No (N)'	System	05 Sep 2020 11:05:20
	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8' User entered 'None (1)'	System	05 Sep 2020 11:05:20
	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:05:16', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e21d2f3-c9cd-4e41-b58d-b4c9a7b0cbe8' User entered '05 Sep 2020 07:05'	System	05 Sep 2020 11:05:20
	System	05 Sep 2020 11:05:20

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 6'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482' User entered 'None (1)'	System	06 Sep 2020 02:06:55
	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482' User entered 'No (N)'	System	06 Sep 2020 02:06:55
	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482' User entered 'No (N)'	System	06 Sep 2020 02:06:55
	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482' User entered 'None (1)'	System	06 Sep 2020 02:06:55
	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '946b2bb4-727e-4f50-bba5-f196fb594482' User entered '05 Sep 2020 22:06'	System	06 Sep 2020 02:06:55
	System	06 Sep 2020 02:06:55

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 7'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered 'None (0)'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:40', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered 'None (0)'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered 'None (0)'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:47', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered 'None (0)'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered 'None (0)'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:23:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered 'None (0)'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:24:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered 'No (N)'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-08-31T16:24:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '125f20db-2109-4d8e-ba0b-57a2c68fdd66' User entered '31 Aug 2020 16:24'	System	31 Aug 2020 20:27:01
	System	31 Aug 2020 20:27:01

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 16:05'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 18:35'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered 'None (0)'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered 'None (0)'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:38:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered 'None (0)'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered 'None (0)'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered 'None (0)'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered 'None (0)'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered 'Yes (Y)'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T05:39:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '82ea9c5a-e84b-46dd-9b18-6cdb1e639cc7' User entered '01 Sep 2020 05:39'	System	01 Sep 2020 09:39:19
	System	01 Sep 2020 09:39:19

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '31 Aug 2020 19:30'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 2'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered 'None (0)'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:18:56', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered 'None (0)'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered 'None (0)'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered 'None (0)'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered 'None (0)'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered 'None (0)'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered 'No (N)'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-01T23:19:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9bde1931-7819-4316-927b-5c51578f976f' User entered '01 Sep 2020 23:19'	System	02 Sep 2020 03:19:49
	System	02 Sep 2020 03:19:49

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 3'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:49', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered 'None (0)'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered 'None (0)'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered 'None (0)'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered 'None (0)'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:35:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered 'None (0)'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered 'None (0)'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered 'No (N)'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T01:36:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '787892e2-54c8-4004-8aea-1311d2d2e741' User entered '03 Sep 2020 01:36'	System	03 Sep 2020 05:36:08
	System	03 Sep 2020 05:36:08

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 4'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:39', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered 'None (0)'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered 'None (0)'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered 'None (0)'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:47', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered 'None (0)'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered 'None (0)'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered 'None (0)'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:44:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered 'No (N)'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-03T20:45:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'e06aae12-a7e5-40be-899f-431e00950f12' User entered '03 Sep 2020 20:45'	System	04 Sep 2020 00:45:07
	System	04 Sep 2020 00:45:07

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 5'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:51:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c' User entered 'None (0)'	System	05 Sep 2020 11:04:53
	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c' User entered 'None (0)'	System	05 Sep 2020 11:04:53
	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c' User entered 'None (0)'	System	05 Sep 2020 11:04:53
	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c' User entered 'None (0)'	System	05 Sep 2020 11:04:53
	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c' User entered 'None (0)'	System	05 Sep 2020 11:04:53
	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T06:52:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c' User entered 'None (0)'	System	05 Sep 2020 11:04:53
	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:04:49', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c'	System	05 Sep 2020 11:04:53
User entered 'No (N)'	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T07:04:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2bfbf876-5885-433e-a1a3-afa0a0647e4c' User entered '05 Sep 2020 07:04'	System	05 Sep 2020 11:04:53
	System	05 Sep 2020 11:04:53

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 6'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered 'None (0)'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered 'None (0)'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered 'None (0)'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered 'None (0)'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered 'None (0)'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered 'None (0)'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered 'No (N)'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-09-05T22:06:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'aef60314-24ea-41a0-98b9-8d311810d94b' User entered '05 Sep 2020 22:06'	System	06 Sep 2020 02:06:40
	System	06 Sep 2020 02:06:40

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 7'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 20:04:44

US3532192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '8 Sep 2020'	Peggy Kettle (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:34

US3532192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	14 Sep 2020 13:37:38

US3532192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	14 Sep 2020 13:37:38

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '14 Sep 2020'	Peggy Kettle (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	14 Sep 2020 13:37:48

US3532192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	14 Sep 2020 13:37:52

US3532192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	14 Sep 2020 13:37:52

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '21 Sep 2020'	Peggy Kettle (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	21 Sep 2020 13:37:42

US3532192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	21 Sep 2020 13:37:47

US3532192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	21 Sep 2020 13:37:47

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 11:17:51
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirm' (Site from System).	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:33:05
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Oct 2020 19:16:17
User entered '6 Oct 2020'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Clinic (Clinic)'	Etza Peters (b) (4)	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'VISIT2'	System	06 Oct 2020 19:16:17

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User accepted default value 'Pre-Dose (PREDOSE)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '6 Oct 2020'	(b) (4) Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '13:51'	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered '6 Oct 2020 13:51'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '98.6' F	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Oral (Oral)'	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '68'	(b) (4) Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'bpm'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '18'	(b) (4) Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'breaths/min'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '156'	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'mmHg'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '89'	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'mmHg'	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User accepted default value 'Post-Dose (POSTDOSE)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 19:54:51
User entered 'Yes (Y)' reason for change: Data Entry Error	System	06 Oct 2020 19:54:51
User opened query 'Data is required. Please complete.' (Site from System).	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	(b) (4)	
	System	06 Oct 2020 19:21:48
	Etza Peters (b) (4)	06 Oct 2020 19:21:48
	(b) (4)	

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '6 Oct 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '15:30' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered '6 Oct 2020 15:30'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '97.6' F reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Oral (Oral)' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User closed query 'Per CDM: Post-dose vitals signs is required per protocol. Please clarify why pulse rate was not done' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:54:56
Query 'Per CDM: Post-dose vitals signs is required per protocol. Please clarify why pulse rate was not done' answered with 'blood pressure machine was acting up and had to take BP manually. Staff forgot to measure HR.' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 16:39:16
User opened query 'Per CDM: Post-dose vitals signs is required per protocol. Please clarify why pulse rate was not done' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:35:55
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 16:41:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 16:41:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:41:32
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'bpm'	System	13 Oct 2020 16:41:32
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '20' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'breaths/min'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '130' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'mmHg'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '70' reason for change: Data Entry Error	Etza Peters (b) (4)	06 Oct 2020 19:54:51
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'mmHg'	System	06 Oct 2020 19:54:51
User entered empty.	System	06 Oct 2020 19:21:48

US3532192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	06 Oct 2020 19:21:56

US3532192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '6 Oct 2020'	Etza Peters (b) (4)	06 Oct 2020 19:21:56

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

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)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '6 Oct 2020'	Etza Peters (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '15:00'	Etza Peters (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered '6 Oct 2020 15:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Left Arm (LEFT ARM)'	Etza Peters (b) (4)	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'ONCE'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:12:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 19:22:26

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '6 Oct 2020'	Etza Peters (b) (4)	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '14:23'	Etza Peters (b) (4)	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered '6 Oct 2020 14:23'	System	06 Oct 2020 19:22:53

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:12:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '6 Oct 2020'	Etza Peters (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Etza Peters (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '13:55'	Etza Peters (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered '6 Oct 2020 13:55'	System	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Etza Peters (b) (4) (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'No (N)'	Etza Peters (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	Etza Peters (b) (4)	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered empty.	System	06 Oct 2020 19:23:08

US3532192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	06 Oct 2020 19:36:35

US3532192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	06 Oct 2020 19:36:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:36:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249' User entered 'Yes (Y)'	System	06 Oct 2020 19:37:23
	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:36:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249' User entered '97.6'	System	06 Oct 2020 19:37:23
	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:36:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249' User entered 'No (N)'	System	06 Oct 2020 19:37:23
	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '61270d7c-285c-473e-94db-4712ad14f249' User entered '06 Oct 2020 15:37'	System	06 Oct 2020 19:37:23
	System	06 Oct 2020 19:37:23

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 15:20'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 17:50'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a' User entered 'Yes (Y)'	System	07 Oct 2020 05:53:22
	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a' User entered '97.4'	System	07 Oct 2020 05:53:22
	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a' User entered 'No (N)'	System	07 Oct 2020 05:53:22
	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c8af0c4b-9ad1-4eb4-9669-b5ab6ea9721a' User entered '07 Oct 2020 01:53'	System	07 Oct 2020 05:53:22
	System	07 Oct 2020 05:53:22

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 18:45'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 2'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:04:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5' User entered 'Yes (Y)'	System	08 Oct 2020 04:05:50
	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5' User entered '98.0'	System	08 Oct 2020 04:05:50
	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5' User entered 'No (N)'	System	08 Oct 2020 04:05:50
	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ed0d5b8e-875b-4780-a0aa-e244b365e6c5' User entered '08 Oct 2020 00:05'	System	08 Oct 2020 04:05:50
	System	08 Oct 2020 04:05:50

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 3'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910' User entered 'Yes (Y)'	System	09 Oct 2020 09:50:17
	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910' User entered '96.8'	System	09 Oct 2020 09:50:17
	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910'	System	09 Oct 2020 09:50:17
User entered 'No (N)'	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0ff37d08-1bb1-409c-a589-cbcbbae5b910' User entered '09 Oct 2020 05:50'	System	09 Oct 2020 09:50:17
	System	09 Oct 2020 09:50:17

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 4'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48' User entered 'Yes (Y)'	System	10 Oct 2020 05:42:54
	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48' User entered '97.6'	System	10 Oct 2020 05:42:54
	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48'	System	10 Oct 2020 05:42:54
User entered 'No (N)'	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '995cafd9-6b1f-4673-931f-ab3d1b62ee48'	System	10 Oct 2020 05:42:54
User entered '10 Oct 2020 01:42'	System	10 Oct 2020 05:42:54

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 5'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a' User entered 'Yes (Y)'	System	11 Oct 2020 10:02:12
	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T06:02:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a' User entered '97.8'	System	11 Oct 2020 10:02:12
	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T06:02:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a' User entered 'No (N)'	System	11 Oct 2020 10:02:12
	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T06:02:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8f3eaba2-4c02-40ff-b521-34fa2d27862a' User entered '11 Oct 2020 06:02'	System	11 Oct 2020 10:02:12
	System	11 Oct 2020 10:02:12

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 6'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:46:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361' User entered 'Yes (Y)'	System	12 Oct 2020 11:47:35
	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361' User entered '98.1'	System	12 Oct 2020 11:47:35
	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361' User entered 'No (N)'	System	12 Oct 2020 11:47:35
	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'f28a18f1-3447-4567-b153-f8440d031361' User entered '12 Oct 2020 07:47'	System	12 Oct 2020 11:47:35
	System	12 Oct 2020 11:47:35

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 7'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93' User entered 'Yes (Y)'	System	13 Oct 2020 02:33:43
	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93' User entered '97.5'	System	13 Oct 2020 02:33:43
	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93'	System	13 Oct 2020 02:33:43
User entered 'No (N)'	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4311ab32-c308-4e1f-9139-5f3b2ad7be93' User entered '12 Oct 2020 22:33'	System	13 Oct 2020 02:33:43
	System	13 Oct 2020 02:33:43

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'None (1)'	System	06 Oct 2020 19:37:38
	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'No (N)'	System	06 Oct 2020 19:37:38
	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:31', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'No (N)'	System	06 Oct 2020 19:37:38
	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered 'None (1)'	System	06 Oct 2020 19:37:38
	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5741f0b8-e306-4af3-9262-538bce66210a' User entered '06 Oct 2020 15:37'	System	06 Oct 2020 19:37:38
	System	06 Oct 2020 19:37:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 15:20'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 17:50'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:34', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196'	System	07 Oct 2020 05:53:52
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196' User entered 'No (N)'	System	07 Oct 2020 05:53:52
	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:43', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196' User entered 'No (N)'	System	07 Oct 2020 05:53:52
	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:47', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196'	System	07 Oct 2020 05:53:52
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:53:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '89d7a545-197f-44b8-b108-bd37a9e70196' User entered '07 Oct 2020 01:53'	System	07 Oct 2020 05:53:52
	System	07 Oct 2020 05:53:52

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 18:45'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 2'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef' User entered 'None (1)'	System	08 Oct 2020 04:06:24
	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:05:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef' User entered 'No (N)'	System	08 Oct 2020 04:06:24
	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:06:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef' User entered 'No (N)'	System	08 Oct 2020 04:06:24
	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:06:09', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef' User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 04:06:24
	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:06:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9b820423-c5ce-4369-ba68-0a5176e3a2ef' User entered '08 Oct 2020 00:06'	System	08 Oct 2020 04:06:24
	System	08 Oct 2020 04:06:24

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 3'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:19', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a' User entered 'None (1)'	System	09 Oct 2020 09:50:38
	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a' User entered 'No (N)'	System	09 Oct 2020 09:50:38
	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a' User entered 'No (N)'	System	09 Oct 2020 09:50:38
	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a' User entered 'None (1)'	System	09 Oct 2020 09:50:38
	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '26da0cd0-42c4-4cc5-a838-23a96975059a' User entered '09 Oct 2020 05:50'	System	09 Oct 2020 09:50:38
	System	09 Oct 2020 09:50:38

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 4'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:42:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d' User entered 'None (1)'	System	10 Oct 2020 05:43:10
	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d' User entered 'No (N)'	System	10 Oct 2020 05:43:10
	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d' User entered 'No (N)'	System	10 Oct 2020 05:43:10
	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d' User entered 'None (1)'	System	10 Oct 2020 05:43:10
	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fb2524bf-85e8-4689-aa3f-91515466612d' User entered '10 Oct 2020 01:43'	System	10 Oct 2020 05:43:10
	System	10 Oct 2020 05:43:10

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 5'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a' User entered 'None (1)'	System	11 Oct 2020 09:59:54
	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:43', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a' User entered 'No (N)'	System	11 Oct 2020 09:59:54
	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:46', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a' User entered 'No (N)'	System	11 Oct 2020 09:59:54
	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a' User entered 'None (1)'	System	11 Oct 2020 09:59:54
	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7fd4ff51-4141-431b-aecd-ac7ad9370a6a' User entered '11 Oct 2020 05:59'	System	11 Oct 2020 09:59:54
	System	11 Oct 2020 09:59:54

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 6'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:39', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b' User entered 'None (1)'	System	12 Oct 2020 11:47:56
	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b' User entered 'No (N)'	System	12 Oct 2020 11:47:56
	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b' User entered 'No (N)'	System	12 Oct 2020 11:47:56
	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b' User entered 'None (1)'	System	12 Oct 2020 11:47:56
	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ad4744fe-3104-4637-ab18-b85da448087b' User entered '12 Oct 2020 07:47'	System	12 Oct 2020 11:47:56
	System	12 Oct 2020 11:47:56

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 7'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:16', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa' User entered 'None (1)'	System	13 Oct 2020 02:33:28
	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa' User entered 'No (N)'	System	13 Oct 2020 02:33:28
	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa' User entered 'No (N)'	System	13 Oct 2020 02:33:28
	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa' User entered 'None (1)'	System	13 Oct 2020 02:33:28
	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '22e49dc3-2ac2-4372-a464-6bd1747672fa' User entered '12 Oct 2020 22:33'	System	13 Oct 2020 02:33:28
	System	13 Oct 2020 02:33:28

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:45', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:49', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:37:56', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'None (0)'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:38:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered 'No (N)'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-06T15:38:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'ecd2bfcd-a93e-4b7f-b486-5898a8586daf' User entered '06 Oct 2020 15:38'	System	06 Oct 2020 19:38:08
	System	06 Oct 2020 19:38:08

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 15:20'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 17:50'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507' User entered 'None (0)'	System	07 Oct 2020 05:55:09
	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:29', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:43', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507' User entered 'None (0)'	System	07 Oct 2020 05:55:09
	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507' User entered 'None (0)'	System	07 Oct 2020 05:55:09
	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:54:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507'	System	07 Oct 2020 05:55:09
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:55:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507' User entered 'No (N)'	System	07 Oct 2020 05:55:09
	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-07T01:55:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bdb549ed-1235-47f7-b45c-5e6eeeb68507' User entered '07 Oct 2020 01:55'	System	07 Oct 2020 05:55:09
	System	07 Oct 2020 05:55:09

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '06 Oct 2020 18:45'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 2'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7' User entered 'None (0)'	System	08 Oct 2020 04:10:10
	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:46', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7'	System	08 Oct 2020 04:10:10
User entered 'No interference with activity (1)'	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:50', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7' User entered 'None (0)'	System	08 Oct 2020 04:10:10
	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:54', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7' User entered 'None (0)'	System	08 Oct 2020 04:10:10
	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:09:57', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7' User entered 'None (0)'	System	08 Oct 2020 04:10:10
	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:10:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7' User entered 'None (0)'	System	08 Oct 2020 04:10:10
	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:10:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7' User entered 'No (N)'	System	08 Oct 2020 04:10:10
	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-08T00:10:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '48c9c5ee-c499-4438-9987-9733f27646b7' User entered '08 Oct 2020 00:10'	System	08 Oct 2020 04:10:10
	System	08 Oct 2020 04:10:10

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 3'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:40', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815' User entered 'None (0)'	System	09 Oct 2020 09:51:19
	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:44', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815' User entered 'None (0)'	System	09 Oct 2020 09:51:19
	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:53', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815' User entered 'None (0)'	System	09 Oct 2020 09:51:19
	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:50:56', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815' User entered 'None (0)'	System	09 Oct 2020 09:51:19
	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815' User entered 'None (0)'	System	09 Oct 2020 09:51:19
	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815' User entered 'None (0)'	System	09 Oct 2020 09:51:19
	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815'	System	09 Oct 2020 09:51:19
User entered 'No (N)'	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-09T05:51:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd7b1debb-bda0-4f3f-9605-a8b7f78df815' User entered '09 Oct 2020 05:51'	System	09 Oct 2020 09:51:19
	System	09 Oct 2020 09:51:19

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 4'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered 'None (0)'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered 'None (0)'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered 'None (0)'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:19', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered 'None (0)'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered 'None (0)'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:25', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered 'None (0)'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered 'Yes (Y)'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-10T01:43:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '36b49366-76bf-4652-b7e7-b06089f294aa' User entered '10 Oct 2020 01:43'	System	10 Oct 2020 05:43:34
	System	10 Oct 2020 05:43:34

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 5'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:21', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09' User entered 'None (0)'	System	11 Oct 2020 09:59:39
	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09' User entered 'None (0)'	System	11 Oct 2020 09:59:39
	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09' User entered 'None (0)'	System	11 Oct 2020 09:59:39
	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09' User entered 'None (0)'	System	11 Oct 2020 09:59:39
	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:28', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09' User entered 'None (0)'	System	11 Oct 2020 09:59:39
	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:30', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09' User entered 'None (0)'	System	11 Oct 2020 09:59:39
	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:33', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09'	System	11 Oct 2020 09:59:39
User entered 'No (N)'	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-11T05:59:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'fa025bf3-bfad-4f1e-b548-42ac5640ab09' User entered '11 Oct 2020 05:59'	System	11 Oct 2020 09:59:39
	System	11 Oct 2020 09:59:39

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 6'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:47:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:03', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:05', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'None (0)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered 'No (N)'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T07:48:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '9069deee-7a29-4c09-bcaf-2700ad13f29f' User entered '12 Oct 2020 07:48'	System	12 Oct 2020 11:48:25
	System	12 Oct 2020 11:48:25

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	06 Oct 2020 19:22:26
User entered 'Day 7'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:32:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered 'None (0)'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:32:58', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered 'None (0)'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:32:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered 'None (0)'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered 'None (0)'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered 'None (0)'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:06', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered 'None (0)'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:11', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered 'No (N)'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-12T22:33:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '4a8cb6fb-bfa7-45dd-bfb3-a26bc19b6450' User entered '12 Oct 2020 22:33'	System	13 Oct 2020 02:33:16
	System	13 Oct 2020 02:33:16

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:22:26

US3532192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:12:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:22:26

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered '13 Oct 2020'	Peggy Kettle (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:30:02

US3532192

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:05:11
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	13 Oct 2020 16:30:06

US3532192

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	13 Oct 2020 16:30:06

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '20 Oct 2020'	(b) (4) Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:31:47

US3532192

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	20 Oct 2020 19:31:54

US3532192

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	20 Oct 2020 19:31:54

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered '28 Oct 2020'	(b) (4) Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	28 Oct 2020 17:06:38

US3532192

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:31
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	28 Oct 2020 17:06:45

US3532192

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	28 Oct 2020 17:06:45

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Nov 2020 20:09:08

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 10:19:14
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'confirm date' (Site from System).	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:31
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Nov 2020 20:09:08
User entered '11 Nov 2020'	Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:08

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Clinic (Clinic)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:08

US3532192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'VISIT3'	System	11 Nov 2020 20:09:08

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'No (N)'	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered empty.	System	11 Nov 2020 20:09:41

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39

US3532192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39

US3532192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'No (N)'	Etza Peters (b) (4)	11 Nov 2020 20:09:54

US3532192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered empty.	Etza Peters (b) (4)	11 Nov 2020 20:09:54

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '11 Nov 2020'	Etza Peters (b) (4)	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered '15:19'	Etza Peters (b) (4)	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered '11 Nov 2020 15:19'	System	11 Nov 2020 21:35:19

US3532192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:17:57
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Nov 2020 21:34:29

US3532192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:57:39
User entered 'I'	System	11 Nov 2020 21:34:29

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 64'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-31T11:20:48', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2343170c-ac00-44a6-af19-4c064a55cd0e' User entered 'No (N)'	System	31 Oct 2020 15:20:57
	System	31 Oct 2020 15:20:57

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-31T11:20:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2343170c-ac00-44a6-af19-4c064a55cd0e' User entered 'No (N)'	System	31 Oct 2020 15:20:57
	System	31 Oct 2020 15:20:57

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-10-31T11:20:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2343170c-ac00-44a6-af19-4c064a55cd0e' User entered '31 Oct 2020 11:20:55'	System	31 Oct 2020 15:20:57
	System	31 Oct 2020 15:20:57

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 71'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-09T01:43:14', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3a9a8f97-d1aa-4d27-812c-213c88e4bb56'	System	09 Nov 2020 06:43:25
User entered 'No (N)'	System	09 Nov 2020 06:43:25

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Have you been exposed to someone with 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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-09T01:43:18', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3a9a8f97-d1aa-4d27-812c-213c88e4bb56'	System	09 Nov 2020 06:43:25
User entered 'No (N)'	System	09 Nov 2020 06:43:25

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-09T01:43:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3a9a8f97-d1aa-4d27-812c-213c88e4bb56' User entered '09 Nov 2020 01:43:23'	System	09 Nov 2020 06:43:25
	System	09 Nov 2020 06:43:25

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered 'Day 78'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-14T02:32:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5194225c-b467-43eb-9abf-d7232d87e7fe' User entered 'No (N)'	System	14 Nov 2020 07:32:32
	System	14 Nov 2020 07:32:32

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-14T02:32:24', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5194225c-b467-43eb-9abf-d7232d87e7fe' User entered 'No (N)'	System	14 Nov 2020 07:32:32
	System	14 Nov 2020 07:32:32

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-11-14T02:32:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5194225c-b467-43eb-9abf-d7232d87e7fe' User entered '14 Nov 2020 02:32:27'	System	14 Nov 2020 07:32:32
	System	14 Nov 2020 07:32:32

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 20:04:44

US3532192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:35:42
Data entry locked.	System	31 Aug 2020 20:04:44
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 20:04:44

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-02T00:01:51', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '6d490518-f8c6-4e12-bb96-74590839b22c' User entered 'Yes (Y)'	System	02 Dec 2020 05:02:41
	System	02 Dec 2020 05:02:41

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-02T00:01:55', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '6d490518-f8c6-4e12-bb96-74590839b22c' User entered 'No (N)'	System	02 Dec 2020 05:02:41
	System	02 Dec 2020 05:02:41

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-02T00:01:59', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '6d490518-f8c6-4e12-bb96-74590839b22c' User entered 'No (N)'	System	02 Dec 2020 05:02:41
	System	02 Dec 2020 05:02:41

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-02T00:02:35', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '6d490518-f8c6-4e12-bb96-74590839b22c' User entered 'No (N)'	System	02 Dec 2020 05:02:41
	System	02 Dec 2020 05:02:41

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-02T00:02:38', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '6d490518-f8c6-4e12-bb96-74590839b22c' User entered '02 Dec 2020 00:02:38'	System	02 Dec 2020 05:02:41
	System	02 Dec 2020 05:02:41

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-09T06:32:41', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '99af9e8c-3d3e-4d08-9885-2a2f4e8482c0'	System	09 Dec 2020 11:33:39
User entered 'Yes (Y)'	System	09 Dec 2020 11:33:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-09T06:33:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '99af9e8c-3d3e-4d08-9885-2a2f4e8482c0'	System	09 Dec 2020 11:33:39
User entered 'No (N)'	System	09 Dec 2020 11:33:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-09T06:33:08', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '99af9e8c-3d3e-4d08-9885-2a2f4e8482c0'	System	09 Dec 2020 11:33:39
User entered 'No (N)'	System	09 Dec 2020 11:33:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-09T06:33:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '99af9e8c-3d3e-4d08-9885-2a2f4e8482c0'	System	09 Dec 2020 11:33:39
User entered 'No (N)'	System	09 Dec 2020 11:33:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-09T06:33:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '99af9e8c-3d3e-4d08-9885-2a2f4e8482c0' User entered '09 Dec 2020 06:33:36'	System	09 Dec 2020 11:33:39
	System	09 Dec 2020 11:33:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-16T04:44:27', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5794beb4-21a5-4ec8-a801-bc34c7283d50'	System	16 Dec 2020 09:44:38
User entered 'No (N)'	System	16 Dec 2020 09:44:38

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-16T04:44:32', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5794beb4-21a5-4ec8-a801-bc34c7283d50'	System	16 Dec 2020 09:44:38
User entered 'No (N)'	System	16 Dec 2020 09:44:38

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-16T04:44:36', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5794beb4-21a5-4ec8-a801-bc34c7283d50' User entered '16 Dec 2020 04:44:36'	System	16 Dec 2020 09:44:38
	System	16 Dec 2020 09:44:38

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-23T00:07:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '451e4aa4-8907-4934-a6e0-2c4e895bbd65' User entered 'No (N)'	System	23 Dec 2020 05:07:19
	System	23 Dec 2020 05:07:19

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-23T00:07:10', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '451e4aa4-8907-4934-a6e0-2c4e895bbd65'	System	23 Dec 2020 05:07:19
User entered 'No (N)'	System	23 Dec 2020 05:07:19

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-23T00:07:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '451e4aa4-8907-4934-a6e0-2c4e895bbd65' User entered '23 Dec 2020 00:07:15'	System	23 Dec 2020 05:07:19
	System	23 Dec 2020 05:07:19

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-30T12:33:16', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'be049b3a-2cc0-41cf-ba05-cfe5c78ba4a5'	System	30 Dec 2020 17:33:25
User entered 'No (N)'	System	30 Dec 2020 17:33:25

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-30T12:33:19', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'be049b3a-2cc0-41cf-ba05-cfe5c78ba4a5'	System	30 Dec 2020 17:33:25
User entered 'No (N)'	System	30 Dec 2020 17:33:25

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2020-12-30T12:33:22', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'be049b3a-2cc0-41cf-ba05-cfe5c78ba4a5' User entered '30 Dec 2020 12:33:22'	System	30 Dec 2020 17:33:25
	System	30 Dec 2020 17:33:25

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-07T13:31:02', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '846c0fc1-8401-499f-90bd-7ced7fc0a543'	System	07 Jan 2021 18:31:18
User entered 'No (N)'	System	07 Jan 2021 18:31:18

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-07T13:31:04', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '846c0fc1-8401-499f-90bd-7ced7fc0a543'	System	07 Jan 2021 18:31:18
User entered 'No (N)'	System	07 Jan 2021 18:31:18

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-07T13:31:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '846c0fc1-8401-499f-90bd-7ced7fc0a543' User entered '07 Jan 2021 13:31:15'	System	07 Jan 2021 18:31:18
	System	07 Jan 2021 18:31:18

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-13T15:43:52', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5237ead3-5899-4db2-9fb6-a0f08014f403' User entered 'Yes (Y)'	System	13 Jan 2021 20:44:28
	System	13 Jan 2021 20:44:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-13T15:43:56', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5237ead3-5899-4db2-9fb6-a0f08014f403'	System	13 Jan 2021 20:44:28
User entered 'No (N)'	System	13 Jan 2021 20:44:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-13T15:44:01', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5237ead3-5899-4db2-9fb6-a0f08014f403'	System	13 Jan 2021 20:44:28
User entered 'No (N)'	System	13 Jan 2021 20:44:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-13T15:44:07', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5237ead3-5899-4db2-9fb6-a0f08014f403'	System	13 Jan 2021 20:44:28
User entered 'No (N)'	System	13 Jan 2021 20:44:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-13T15:44:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5237ead3-5899-4db2-9fb6-a0f08014f403' User entered '13 Jan 2021 15:44:12'	System	13 Jan 2021 20:44:28
	System	13 Jan 2021 20:44:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-20T00:59:37', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8e3480e5-3e75-4df2-a3b3-38b9ac3fed16'	System	20 Jan 2021 05:59:47
User entered 'No (N)'	System	20 Jan 2021 05:59:47

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-20T00:59:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8e3480e5-3e75-4df2-a3b3-38b9ac3fed16'	System	20 Jan 2021 05:59:47
User entered 'No (N)'	System	20 Jan 2021 05:59:47

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-20T00:59:46', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '8e3480e5-3e75-4df2-a3b3-38b9ac3fed16' User entered '20 Jan 2021 00:59:46'	System	20 Jan 2021 05:59:47
	System	20 Jan 2021 05:59:47

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-27T21:43:10', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'eab1f429-beea-4eab-aaa7-ac5c4d7972d2'	System	28 Jan 2021 02:43:17
User entered 'No (N)'	System	28 Jan 2021 02:43:17

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-27T21:43:12', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'eab1f429-beea-4eab-aaa7-ac5c4d7972d2'	System	28 Jan 2021 02:43:17
User entered 'No (N)'	System	28 Jan 2021 02:43:17

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-01-27T21:43:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'eab1f429-beea-4eab-aaa7-ac5c4d7972d2'	System	28 Jan 2021 02:43:17
User entered '27 Jan 2021 21:43:15'	System	28 Jan 2021 02:43:17

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-03T08:18:15', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c359a067-8a26-4607-a090-b2012a9cfbca' User entered 'No (N)'	System	03 Feb 2021 13:18:30
	System	03 Feb 2021 13:18:30

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-03T08:18:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c359a067-8a26-4607-a090-b2012a9cfbca' User entered 'No (N)'	System	03 Feb 2021 13:18:30

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-03T08:18:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'c359a067-8a26-4607-a090-b2012a9cfbca' User entered '03 Feb 2021 08:18:26'	System	03 Feb 2021 13:18:30
	System	03 Feb 2021 13:18:30

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-10T00:56:13', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e33e69f-4649-48b1-b216-a41e294aac05' User entered 'No (N)'	System	10 Feb 2021 05:56:28
	System	10 Feb 2021 05:56:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-10T00:56:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e33e69f-4649-48b1-b216-a41e294aac05' User entered 'No (N)'	System	10 Feb 2021 05:56:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-10T00:56:26', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '0e33e69f-4649-48b1-b216-a41e294aac05' User entered '10 Feb 2021 00:56:26'	System	10 Feb 2021 05:56:28
	System	10 Feb 2021 05:56:28

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-17T01:51:42', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5dd7f170-d8b8-4d03-9783-f834cca0d0a2' User entered 'No (N)'	System	17 Feb 2021 06:51:51
	System	17 Feb 2021 06:51:51

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-17T01:51:46', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5dd7f170-d8b8-4d03-9783-f834cca0d0a2' User entered 'No (N)'	System	17 Feb 2021 06:51:51
	System	17 Feb 2021 06:51:51

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-17T01:51:49', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '5dd7f170-d8b8-4d03-9783-f834cca0d0a2' User entered '17 Feb 2021 01:51:49'	System	17 Feb 2021 06:51:51
	System	17 Feb 2021 06:51:51

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-24T00:01:17', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '93dc42d7-8804-42f0-93b4-d751ed5ffa62'	System	24 Feb 2021 05:03:31
User entered 'No (N)'	System	24 Feb 2021 05:03:31

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-24T00:01:20', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '93dc42d7-8804-42f0-93b4-d751ed5ffa62'	System	24 Feb 2021 05:03:31
User entered 'No (N)'	System	24 Feb 2021 05:03:31

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-02-24T00:01:23', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '93dc42d7-8804-42f0-93b4-d751ed5ffa62'	System	24 Feb 2021 05:03:31
User entered '24 Feb 2021 00:01:23'	System	24 Feb 2021 05:03:31

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-03T00:02:22-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '013d1de8-eea8-4d2c-b301-e5231ec0bd59' User entered 'No (N)'	System	03 Mar 2021 05:03:39
	System	03 Mar 2021 05:03:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-03T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '013d1de8-eea8-4d2c-b301-e5231ec0bd59'	System	03 Mar 2021 05:03:39
User entered 'No (N)'	System	03 Mar 2021 05:03:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-03T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '013d1de8-eea8-4d2c-b301-e5231ec0bd59' User entered '03 Mar 2021 00:02:27'	System	03 Mar 2021 05:03:39
	System	03 Mar 2021 05:03:39

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-10T00:04:37-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b8f12d43-4218-4824-87ee-2f2751da759b'	System	10 Mar 2021 05:06:00
User entered 'No (N)'	System	10 Mar 2021 05:06:00

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-10T00:04:40-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b8f12d43-4218-4824-87ee-2f2751da759b'	System	10 Mar 2021 05:06:00
User entered 'No (N)'	System	10 Mar 2021 05:06:00

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-10T00:04:42-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'b8f12d43-4218-4824-87ee-2f2751da759b' User entered '10 Mar 2021 00:04:42'	System	10 Mar 2021 05:06:00
	System	10 Mar 2021 05:06:00

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-17T02:14:07-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bed45a04-cad6-48c0-884b-c1905de055c0'	System	17 Mar 2021 06:14:37
User entered 'Yes (Y)'	System	17 Mar 2021 06:14:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-17T02:14:11-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bed45a04-cad6-48c0-884b-c1905de055c0'	System	17 Mar 2021 06:14:37
User entered 'No (N)'	System	17 Mar 2021 06:14:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-17T02:14:19-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bed45a04-cad6-48c0-884b-c1905de055c0'	System	17 Mar 2021 06:14:37
User entered 'No (N)'	System	17 Mar 2021 06:14:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-17T02:14:30-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bed45a04-cad6-48c0-884b-c1905de055c0'	System	17 Mar 2021 06:14:37
User entered 'No (N)'	System	17 Mar 2021 06:14:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-17T02:14:34-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'bed45a04-cad6-48c0-884b-c1905de055c0' User entered '17 Mar 2021 02:14:34'	System	17 Mar 2021 06:14:37
	System	17 Mar 2021 06:14:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-24T01:46:40-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cf26b7a3-468c-4ca6-bcd9-fd410bf1cce7'	System	24 Mar 2021 05:46:53
User entered 'No (N)'	System	24 Mar 2021 05:46:53

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-24T01:46:47-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cf26b7a3-468c-4ca6-bcd9-fd410bf1cce7'	System	24 Mar 2021 05:46:53
User entered 'No (N)'	System	24 Mar 2021 05:46:53

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-24T01:46:51-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'cf26b7a3-468c-4ca6-bcd9-fd410bf1cce7' User entered '24 Mar 2021 01:46:51'	System	24 Mar 2021 05:46:53

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-31T01:44:29-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd573f526-7158-485e-a1c3-16c2ac8b42eb'	System	31 Mar 2021 05:44:40
User entered 'No (N)'	System	31 Mar 2021 05:44:40

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-31T01:44:32-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd573f526-7158-485e-a1c3-16c2ac8b42eb'	System	31 Mar 2021 05:44:40
User entered 'No (N)'	System	31 Mar 2021 05:44:40

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-31T01:44:34-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd573f526-7158-485e-a1c3-16c2ac8b42eb' User entered '31 Mar 2021 01:44:34'	System	31 Mar 2021 05:44:40
	System	31 Mar 2021 05:44:40

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-07T01:58:42-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '363a1e9a-ffb2-4fa3-acae-2cb9edb2f4f8'	System	07 Apr 2021 05:58:50
User entered 'No (N)'	System	07 Apr 2021 05:58:50

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-07T01:58:45-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '363a1e9a-ffb2-4fa3-acae-2cb9edb2f4f8'	System	07 Apr 2021 05:58:50
User entered 'No (N)'	System	07 Apr 2021 05:58:50

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-07T01:58:48-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '363a1e9a-ffb2-4fa3-acae-2cb9edb2f4f8'	System	07 Apr 2021 05:58:50
User entered '07 Apr 2021 01:58:48'	System	07 Apr 2021 05:58:50

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-14T13:52:29-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7d739f8f-3a35-41ce-85b5-90e28c1358fa' User entered 'No (N)'	System	14 Apr 2021 17:52:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-14T13:52:32-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7d739f8f-3a35-41ce-85b5-90e28c1358fa' User entered 'No (N)'	System	14 Apr 2021 17:52:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-14T13:52:35-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '7d739f8f-3a35-41ce-85b5-90e28c1358fa' User entered '14 Apr 2021 13:52:35'	System	14 Apr 2021 17:52:37
	System	14 Apr 2021 17:52:37

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-21T14:55:04-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd30f7d77-9781-4fe7-b0ac-2885febdf2ee' User entered 'No (N)'	System	21 Apr 2021 18:55:25

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-21T14:55:18-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd30f7d77-9781-4fe7-b0ac-2885febdf2ee' User entered 'No (N)'	System	21 Apr 2021 18:55:25

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-21T14:55:21-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: 'd30f7d77-9781-4fe7-b0ac-2885febdf2ee' User entered '21 Apr 2021 14:55:21'	System	21 Apr 2021 18:55:25
	System	21 Apr 2021 18:55:25

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-29T14:41:41-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2eaa6716-90cf-453f-b95b-7d5d4a1dae53'	System	29 Apr 2021 18:42:00
User entered 'No (N)'	System	29 Apr 2021 18:42:00

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

Have you been exposed to someone with 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 (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-29T14:41:44-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2eaa6716-90cf-453f-b95b-7d5d4a1dae53'	System	29 Apr 2021 18:42:00
User entered 'No (N)'	System	29 Apr 2021 18:42:00

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-04-29T14:41:46-04:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '2eaa6716-90cf-453f-b95b-7d5d4a1dae53'	System	29 Apr 2021 18:42:00
User entered '29 Apr 2021 14:41:46'	System	29 Apr 2021 18:42:00

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:09:29

US3532192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:12:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:09:29
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:09:29

US3532192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:12:18

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 10:11:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-02T16:40:37-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3bd17698-6c7b-4520-867c-82b496ab5f70'	System	02 Mar 2021 21:40:45
User entered 'No (N)'	System	02 Mar 2021 21:40:45

US3532192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:12:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C59EF8BE-7997-41EE-918F-4BDF16D292A3)', Time: '2021-03-02T16:40:41-05:00', User OID: 'PatientReportedOutcome (US3532192)', ODM File OID: '3bd17698-6c7b-4520-867c-82b496ab5f70'	System	02 Mar 2021 21:40:45
User entered '02 Mar 2021 16:40:41'	System	02 Mar 2021 21:40:45

US3532192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:41:57
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	01 Dec 2020 19:12:38

US3532192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:41:57
User entered '1 Dec 2020'	Peggy Kettle (b) (4)	01 Dec 2020 19:12:38

US3532192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:41:57
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4)	01 Dec 2020 19:12:38

US3532192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:41:57
User entered empty.	Peggy Kettle (b) (4)	01 Dec 2020 19:12:38

US3532192

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:41:57
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	01 Dec 2020 19:12:47

US3532192

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:42:31
User entered 'I'	System	01 Dec 2020 19:12:47

US3532192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	05 Jan 2021 19:27:07

US3532192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '5 Jan 2021'	Peggy Kettle (b) (4)	05 Jan 2021 19:27:07

US3532192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4)	05 Jan 2021 19:27:07

US3532192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Peggy Kettle (b) (4)	05 Jan 2021 19:27:07

US3532192

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	05 Jan 2021 19:27:14

US3532192

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered 'I'	System	05 Jan 2021 19:27:14

US3532192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	01 Feb 2021 22:01:18

US3532192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '1 Feb 2021'	Peggy Kettle (b) (4)	01 Feb 2021 22:01:18

US3532192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4)	01 Feb 2021 22:01:18

US3532192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Peggy Kettle (b) (4)	01 Feb 2021 22:01:18

US3532192

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	01 Feb 2021 22:01:23

US3532192

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered 'I'	System	01 Feb 2021 22:01:23

US3532192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	02 Mar 2021 21:44:54

US3532192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '2 Mar 2021'	Peggy Kettle (b) (4)	02 Mar 2021 21:44:54

US3532192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Contact Made (CONTACT MADE)'	Peggy Kettle (b) (4)	02 Mar 2021 21:44:54

US3532192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Peggy Kettle (b) (4)	02 Mar 2021 21:44:54

US3532192

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	02 Mar 2021 21:44:59

US3532192

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered 'I'	System	02 Mar 2021 21:44:59

US3532192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:22
User signature succeeded.	Evan Anderson (b) (4)	30 Apr 2021 08:42:13
User closed query 'Per CDM: Data is required. Please Complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 04:14:32
Query 'Per CDM: Data is required. Please Complete. ' answered with 'done' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	26 Apr 2021 17:38:27
Signature has been broken.	Kathy Stephens (b) (4) (b) (4)	26 Apr 2021 17:38:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	26 Apr 2021 17:38:10
User opened query 'Per CDM: Data is required. Please Complete. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 22:15:49
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:08:31
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:14:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 08:22:27
Query 'Data is required. Please complete.' answered with 'dat entry error' (Site from System).	Peggy Kettle (b) (4) (b) (4)	17 Mar 2021 15:13:18
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 15:13:07
User entered empty; reason for change Data Entry Error	Peggy Kettle (b) (4) (b) (4)	17 Mar 2021 15:13:07
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	17 Mar 2021 14:49:23

US3532192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:22
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:08:31
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '29 Mar 2021' reason for change: Data Entry Error	(b) (4) Teresa Ball (b) (4)	29 Mar 2021 16:16:05
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) System	17 Mar 2021 15:13:07
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Mar 2021 15:13:07
User entered empty; reason for change Data Entry Error	Peggy Kettle (b) (4) (b) (4)	17 Mar 2021 15:13:07
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	17 Mar 2021 14:49:23
User entered '17 Mar 2021'	Peggy Kettle (b) (4) (b) (4)	17 Mar 2021 14:49:23

US3532192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:22
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:08:31
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Clinic (Clinic)'	Peggy Kettle (b) (4)	17 Mar 2021 14:49:23

US3532192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:22
User entered 'VISIT4'	System	26 Apr 2021 17:38:10
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:08:31
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered empty.	System	17 Mar 2021 15:13:07
User entered 'VISIT4'	System	17 Mar 2021 14:49:23

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'No (N)'	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered empty.	System	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered empty.	System	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered empty.	System	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered empty.	System	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered empty.	System	29 Mar 2021 16:17:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15

US3532192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:12:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15

US3532192

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'No (N)'	Teresa Ball (b) (4)	29 Mar 2021 16:18:13

US3532192

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:12:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	Teresa Ball (b) (4)	29 Mar 2021 16:18:13

US3532192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Teresa Ball (b) (4)	29 Mar 2021 16:18:42

US3532192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '29 Mar 2021'	Teresa Ball (b) (4)	29 Mar 2021 16:18:42

US3532192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '09:58'	Teresa Ball (b) (4)	29 Mar 2021 16:18:42

US3532192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered '29 Mar 2021 09:58'	System	29 Mar 2021 16:18:42

US3532192

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Teresa Ball (b) (4)	29 Mar 2021 16:18:51

US3532192

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:57:15
User entered 'I'	System	29 Mar 2021 16:18:51

US3532192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 20:22:04
	(b) (4)	
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	03 May 2021 17:13:19
	(b) (4)	

US3532192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 20:22:04
	(b) (4)	
User entered '1 May 2021'	Peggy Kettle (b) (4)	03 May 2021 17:13:19
	(b) (4)	

US3532192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 20:22:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	03 May 2021 17:13:19

US3532192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:12:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 20:22:04
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	03 May 2021 17:13:19

US3532192

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 20:22:04
	(b) (4)	
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	03 May 2021 17:13:09
	(b) (4)	

US3532192

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:12:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:13:09

US3532192

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

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Teresa Ball (b) (4)	25 Jan 2021 15:50:26

US3532192

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

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '25 Jan 2021'	Teresa Ball (b) (4)	25 Jan 2021 15:50:26

US3532192

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

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[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 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Clinic (Clinic)'	Teresa Ball (b) (4)	25 Jan 2021 15:50:26

US3532192

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

Form: Visit Date

Generated On: 10 Jun 2021 08:12:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 15:50:26

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '25 Jan 2021'	Teresa Ball (b) (4)	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:39:40

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Teresa Ball (b) (4)	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:39:40

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '25 Jan 2021'	Teresa Ball (b) (4)	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Ball (b) (4)	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Ball (b) (4)	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Ball (b) (4)	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'No (N)'	Teresa Ball (b) (4)	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	25 Jan 2021 15:50:49

US3532192

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

Form: Unblinding

Generated On: 10 Jun 2021 08:12:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered empty.	System	25 Jan 2021 15:50:49

US3532192

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Teresa Ball (b) (4)	25 Jan 2021 15:51:12

US3532192

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '25 Jan 2021'	Teresa Ball (b) (4)	25 Jan 2021 15:51:12

US3532192

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '10:02'	Teresa Ball (b) (4)	25 Jan 2021 15:51:12

US3532192

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:12:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '25 Jan 2021 10:02'	System	25 Jan 2021 15:51:12

US3532192

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Teresa Ball (b) (4)	25 Jan 2021 15:51:32

US3532192

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '25 Jan 2021'	Teresa Ball (b) (4)	25 Jan 2021 15:51:32

US3532192

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '10:07'	Teresa Ball (b) (4)	25 Jan 2021 15:51:32

US3532192

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:12:18

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:34:41
User entered '25 Jan 2021 10:07'	System	25 Jan 2021 15:51:32

US3532192

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:12:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:53
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:23:56
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:46:28

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of INTERMITTENT NOSEBLEEDS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:07:32
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of INTERMITTENT NOSEBLEEDS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'Nosebleed is still intermittent and not worsening (not more often or more severe) Should we remove this as an AE or leave it as grade 1?' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	26 Jan 2021 16:27:08
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of INTERMITTENT NOSEBLEEDS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 04:58:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nosebleed - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:48:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:48:39
Data point term sent to Coder	System	20 Oct 2020 19:48:01
User entered 'Nosebleed'	Peggy Kettle (b) (4) (b) (4)	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '19 Oct 2020'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User entered empty.	System	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
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	22 Oct 2020 20:49:33
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	22 Oct 2020 20:49:33
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	22 Oct 2020 20:48:53
User entered '20 Oct 2020'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User entered empty.	System	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'None (NONE)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'I'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:49:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:48:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:48:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:47:12
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
User entered 'Subject has history of nosebleeds since 2014. Has seen a doctor for them in the past but no known etiology. Not related to vaccine, due to prior history' reason for change: Data Entry Error	Peggy Kettle (b) (4)	22 Oct 2020 20:48:53
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	20 Oct 2020 19:47:12
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User entered '0'	System	20 Oct 2020 19:47:12

US3532192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14
User entered '0'	System	20 Oct 2020 19:47:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:12:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:58
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:17
User entered	System	13 Nov 2020 13:17:13
'USA-US077-2020-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 13:17:13

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Clear cell renal cell carcinoma, LLT: Clear cell renal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 06:20:44
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 06:20:44
User closed query 'PV Query: Please consider updating event term to final diagnosis, including staging. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 15:33:18
Query 'PV Query: Please consider updating event term to final diagnosis, including staging. Please leave query open until information is available. ' answered with 'added' (Site from Safety).	Peggy Kettle (b) (4)	03 Dec 2020 17:30:52
Data point term sent to Coder	System	03 Dec 2020 15:27:53
Coding entries removed.	Peggy Kettle (b) (4)	03 Dec 2020 15:27:15
User entered 'KIDNEY CANCER, RIGHT KIDNEY Clear cell renal cell carcinoma, WHO/ISUP Grade 3' reason for change: New Information	Peggy Kettle (b) (4)	03 Dec 2020 15:27:15
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Kidney cancer - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 08:00:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 08:00:54
Data point term sent to Coder	System	01 Dec 2020 17:48:08
Coding entries removed.	Peggy Kettle (b) (4)	01 Dec 2020 17:47:31
User entered 'KIDNEY CANCER, RIGHT KIDNEY' reason for change: New Information	Peggy Kettle (b) (4)	01 Dec 2020 17:47:31

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating event term to final diagnosis, including staging. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:24:50
User closed query 'PV Query: Please consider updating event term to final diagnosis, including staging.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:44:44
Query 'PV Query: Please consider updating event term to final diagnosis, including staging.' answered with 'new diagnosis of cancer awaiting kidney removal for final staging' (Site from Safety).	Laila Hussaini (b) (4) (b) (4)	24 Nov 2020 17:03:59
User opened query 'PV Query: Please consider updating event term to final diagnosis, including staging.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:40
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Kidney cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:17:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:17:33
Data point term sent to Coder	System	12 Nov 2020 16:17:12
User entered 'kidney cancer'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:02:22
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:02:24
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:02:26
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:32
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 22:04:38
User entered '09 Oct 2020'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:35
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:37
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered 'No (N)' reason for change: New Information	(b) (4) Peggy Kettle (b) (4)	03 Dec 2020 19:19:24
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:40
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered '23 Nov 2020' reason for change: New Information	(b) (4) Peggy Kettle (b) (4)	03 Dec 2020 19:19:24
User entered empty.	(b) (4) Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:46
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered empty.	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 22:35:15
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)	20 Nov 2020 22:22:47
User entered empty.	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:48
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:09:50
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:08:16
User entered '0'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:38:00
User closed query 'please verify and confirm source and eDC updates' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:37:58
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
Query 'please verify and confirm source and eDC updates' answered with 'UPDATED' (Site from CRA).	(b) (4) Peggy Kettle (b) (4)	08 Mar 2021 13:57:47
User entered '0' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	08 Mar 2021 13:42:42
User opened query 'please verify and confirm source and eDC updates' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:12
User entered '1'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:38:07
User closed query 'please confirm source page is updated' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:38:04
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
Query 'please confirm source page is updated' answered with 'UPDATED SOURCE' (Site from CRA).	Peggy Kettle (b) (4)	08 Mar 2021 13:58:03
User opened query 'please confirm source page is updated' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:03:04
User closed query 'per source = hospitalization, please verify' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:03:04
Query 'per source = hospitalization, please verify' answered with 'HOSPITALIZATION DATES ADDED' (Site from CRA).	Peggy Kettle (b) (4)	04 Mar 2021 21:25:44
User entered '1' reason for change: Data Entry Error	Peggy Kettle (b) (4)	04 Mar 2021 21:25:13
User opened query 'per source = hospitalization, please verify' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 21:02:08
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).		12 Nov 2020 16:17:24
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		12 Nov 2020 16:17:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Nov 2020 16:16:30
User entered '0'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'please confirm source has been updated' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:10:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:10:03
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
Query 'please confirm source has been updated' answered with 'UPDATED SOURCE' (Site from CRA).	Peggy Kettle (b) (4)	08 Mar 2021 13:58:12
User opened query 'please confirm source has been updated' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:03:15
User closed query 'please update' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:03:15
Query 'please update' answered with 'UPDATED' (Site from CRA).	Peggy Kettle (b) (4)	04 Mar 2021 21:25:51
User entered '18 Nov 2020' reason for change: New Information	Peggy Kettle (b) (4)	04 Mar 2021 21:25:13
User opened query 'please update' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 21:02:27
User entered empty.	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:03:22
User entered '23 Nov 2020' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:25:13
User entered empty.	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:03:25
User entered 'Yes (Y)' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:25:13
User entered empty; reason for change Data Entry Error	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:17:24
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:03:27
User entered '1' reason for change: New Information	Peggy Kettle (b) (4)	04 Mar 2021 21:25:13
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:03:28
User entered '0'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:03:30
User entered '0'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:03:35
User entered 'I'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:03:37
User entered 'Not Related (NOT RELATED)'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:03:44
User entered 'Not Related (NOT RELATED)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:03:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

None

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:03:57
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.	(b) (4), (b) (6)	03 Dec 2020 06:52:25
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.	Peggy Kettle (b) (4)	01 Dec 2020 17:45:22
' answered with 'procedure added now that information is available' (Site from DM).	(b) (4)	
User entered '0' reason for change: New Information	Peggy Kettle (b) (4)	01 Dec 2020 17:44:35
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.	(b) (4), (b) (6)	27 Nov 2020 14:46:09
' (Site from DM).		
User entered '1'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:04:00
User entered '1' reason for change: New Information	Peggy Kettle (b) (4)	04 Mar 2021 21:25:13
User entered '0'	(b) (4)	
	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:04:02
User entered '1' reason for change: New Information	Peggy Kettle (b) (4)	01 Dec 2020 17:44:35
User entered '0'	(b) (4)	
	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:04:07
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until outcome has been achieved. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 15:33:14
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until outcome has been achieved. ' answered with 'kidney/cancer removed and subject released from hospital on 11/23/20' (Site from Safety).	Peggy Kettle (b) (4)	03 Dec 2020 19:19:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Peggy Kettle (b) (4)	03 Dec 2020 19:19:24
New Information		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Peggy Kettle (b) (4)	03 Dec 2020 17:42:17
New Information		
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until outcome has been achieved. ' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:21:37
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.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:20:42
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)	29 Nov 2020 11:20:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:44:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'awaiting final outcome' (Site from Safety).	Laila Hussaini (b) (4) (b) (4)	24 Nov 2020 17:06:19
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 22:22:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:04:09
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	12 Nov 2020 16:16:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 15:40:56
User closed query 'Please updated Narrative note to include final details' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:40:54
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
Query 'Please updated Narrative note to include final details' answered with 'UPDATED WITH KIDNEY REMOVAL' (Site from CRA).	(b) (4) Peggy Kettle (b) (4)	08 Mar 2021 13:58:24
User entered 'NEW DIAGNOSIS OF CANCER. RIGHT KIDNEY REMOVED. DIAGNOSED WHEN HE WAS UNDERGOING WORKUP FOR KIDNEY TRANSPLANT. NOT RELATED TO VACCINE. HAD BASELINE KIDNEY FAILURE' reason for change: New Information	Peggy Kettle (b) (4)	08 Mar 2021 13:57:35
User opened query 'Please updated Narrative note to include final details' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:04:54
User closed query 'Per DM CLR: Narrative = UNDERGOING WORKUP FOR KIDNEY TRANSPLANT. Please review and confirm what are these "WORK-UPS" and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:23:16
Query 'Per DM CLR: Narrative = UNDERGOING WORKUP FOR KIDNEY TRANSPLANT. Please review and confirm what are these "WORK-UPS" and ensure that this is captured in the appropriate eCRF.	Peggy Kettle (b) (4)	19 Feb 2021 14:16:45
' answered with 'routine follow up with kidney doctor for ongoing kidney failure ' (Site from DM).		
User opened query 'Per DM CLR: Narrative = UNDERGOING WORKUP FOR KIDNEY TRANSPLANT. Please review and confirm what are these "WORK-UPS" and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:11:06

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:53
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:51
User closed query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:49
User closed query 'PV Query: After the subject has seen their oncologist please provide the treatment plan. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' answered with 'pathology reports sent' (Site from Safety).	Peggy Kettle (b) (4) (b) (4)	08 Dec 2020 20:07:55
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). Please leave query open until information is available.' answered with 'Treatment was right radical nephrectomy, follow up in 6 months' (Site from Safety).	Peggy Kettle (b) (4) (b) (4)	08 Dec 2020 20:07:43

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available. ' answered with 'Subject did not see oncologist. Follow up visit note from surgeon sent' (Site from Safety).	Peggy Kettle (b) (4) (b) (4)	08 Dec 2020 20:06:18
Query 'PV Query: After the subject has seen their oncologist please provide the treatment plan. Please leave query open until information is available. ' answered with 'subject was not referred to oncologist. See Office note Dated 12/7/20' (Site from Safety).	Peggy Kettle (b) (4) (b) (4)	08 Dec 2020 20:05:36
User closed query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right). Please leave query open until information is available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 15:33:10
User closed query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 15:33:08
Query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available. ' answered with 'pathology from resected kidney sent 12/3/2020' (Site from Safety).	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 18:48:20
Query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right). Please leave query open until information is available. Please leave query open until information is available.' answered with 'right kidney was removed on 11/18/2020' (Site from Safety).	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 15:04:40

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'NEW DIAGNOSIS OF CANCER. AWAITING RIGHT KIDNEY REMOVAL. DIAGNOSED WHEN HE WAS UNDERGOING WORKUP FOR KIDNEY TRANSPLANT. NOT RELATED TO VACCINE. HAD BASELINE KIDNEY FAILURE' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 17:46:59
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). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:28:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:27:51
User opened query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right). Please leave query open until information is available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:27:06
User opened query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:25:31
User opened query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:24:20
User opened query 'PV Query: After the subject has seen their oncologist please provide the treatment plan. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:23:57

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:45:41
User closed query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:45:38
User closed query 'PV Query: Has the subject seen an oncologist or have plans to see one in the future? If so, what is the treatment plan?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:45:24
User closed query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right).' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:45:14
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:45:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:45:07
Query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'no notes provided by subject to date' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:08:27
Query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'no biopsy performed to date.' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:08:16
Query 'PV Query: Has the subject seen an oncologist or have plans to see one in the future? If so, what is the treatment plan?' answered with 'has oncology appointment scheduled' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:07:47

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Audit	User	Time (GMT)
Query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right).' answered with 'waiting for oncology appointment' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:07:36
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 'no updated provided by subject yet' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:07:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no update at the time' (Site from Safety).	Laila Hussaini (b) (4)	24 Nov 2020 17:06:36
User opened query 'PV Query: Please provide Oncology notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:48
User opened query 'PV Query: Was a biopsy performed? If so, please provide results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:30
User opened query 'PV Query: Has the subject seen an oncologist or have plans to see one in the future? If so, what is the treatment plan?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:23
User opened query 'PV Query: Please provide the date of kidney removal and clarify which kidney was removed (left vs right).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:17
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:09

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:23:02
User entered 'New diagnosis of cancer. Awaiting kidney removal. Diagnosed wehn he was undergoing workup for kidney transplant. Not related to vaccine. Had baseline kidney failure'	Peggy Kettle (b) (4)	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:12:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 21:25:13
User entered '0'	System	12 Nov 2020 16:16:30

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:09:13
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:24
User entered	(b) (4), (b) (6)	08 Dec 2020 20:40:24
'USA-US077-2020-mRNA-1273-P301000012'		
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:17
User entered	System	02 Dec 2020 15:41:14
'USA-US077-2020-mRNA-1273-P301000014'		
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 15:41:14

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Peritoneal and retroperitoneal conditions, HLT: Peritoneal and retroperitoneal haemorrhages, PT: Retroperitoneal haemorrhage, LLT: Retroperitoneal bleed - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 18:56:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 18:56:52
Data point term sent to Coder	System	01 Dec 2020 18:55:30
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:17
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:20
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:22
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:23
User entered '18 Nov 2020'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:27
User entered empty.	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:29
User entered 'No (N)'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:30
User entered '20 Nov 2020'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:33
User entered empty.	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:34
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 17:47:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 17:47:23
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 17:47:23
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 18:55:22
User entered empty.	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:37
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 15:58:17
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'serious due to prolongation of hospitalization' (Site from Safety).	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 17:51:04
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	03 Dec 2020 17:48:55
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:10:06
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	01 Dec 2020 18:55:22
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:41
User entered '0'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:42
User entered '0'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:43
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).		03 Dec 2020 17:48:55
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).		03 Dec 2020 17:48:55
User entered '1' reason for change: Data Entry Error	Peggy Kettle (b) (4)	03 Dec 2020 17:48:55
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	03 Dec 2020 17:47:23
User entered '0'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:46
User entered '18 Nov 2020' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 17:47:23
User entered empty.	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:48
User entered '23 Nov 2020' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 17:47:23
User entered empty.	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:09:54
User entered 'Yes (Y)' reason for change: New Information	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 17:47:23
User entered empty.	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:55
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	03 Dec 2020 17:48:55
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	03 Dec 2020 17:48:55
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	03 Dec 2020 17:47:23
User entered '1' reason for change: New Information	Peggy Kettle (b) (4)	03 Dec 2020 17:47:23
User entered empty.	(b) (4)	
	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:59
User entered '0'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:00
User entered '0'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:02
User entered '0'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:04
User entered 'Not Related (NOT RELATED)'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:07
User entered 'Not Related (NOT RELATED)'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:09
User entered 'Not Applicable (NOT APPLICABLE)'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:13
User entered '0'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:16
User entered '0'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:18
User entered 'I'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Peggy Kettle (b) (4)	01 Dec 2020 18:55:22
	(b) (4)	

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:21
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:24
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Dec 2020 17:47:23
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Dec 2020 17:47:23
User entered 'occurred after surgery. know complication from nephrectomy. Not related to vaccine or vaccine study procedures. Subject had bleeding post Right nephrectomy. Exploratory lap done which found large retroperitoneal hematoma. Hematoma was evacuated and bleeding at hilum successfully clipped.' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	03 Dec 2020 17:47:23
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Dec 2020 18:55:22
User entered empty.	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 18:55:22

US3532192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:12:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Dec 2020 17:47:23

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:12:18

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:53
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	31 Aug 2020 20:10:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 20:45:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:45:40
Data point term sent to Coder	System	31 Aug 2020 20:44:38
Data point term sent to Coder	System	31 Aug 2020 20:28:08
User entered 'hydralazine'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'hypertension'	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 04:12:44
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'added' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:31:52
User entered '100' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:31:45
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:54:08
User entered '2'	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:31:45
	(b) (4)	
User entered 'tablet (TABLET)'	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	13 Oct 2020 16:31:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'once daily (QD)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 05:33:40
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'corrected start date of MH' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:33:39
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:54:06
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	31 Aug 2020 20:44:08
User entered 'un UNK 2014' reason for change: Data Entry Error	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:08
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4) (b) (4)	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:44:08
User entered 'No (N)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	31 Aug 2020 20:44:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:27:15
User entered empty.	Peggy Kettle (b) (4)	31 Aug 2020 20:27:15
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Oct 2020 16:31:45
User entered '1'	System	31 Aug 2020 20:44:08
User entered empty.	System	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:44:08
User entered empty.	System	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:44:08
User entered empty.	System	31 Aug 2020 20:27:15

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: OTHER DIURETICS, PRODUCT: ISOSORBIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 20:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:46:42
Data point term sent to Coder	System	31 Aug 2020 20:45:38
User entered 'isosorbide'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'hypertension'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 60 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:11:36
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 60 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:34:21
User entered '90' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:34:08
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 60 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:54:43
User entered '3'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:34:08
	(b) (4)	
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:11:12
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH date corrected' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:40:43
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:54:27
User entered 'un UNK 2014'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:44:49
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:44:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	31 Aug 2020 20:46:41
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	31 Aug 2020 20:46:41
Data point term sent to Coders	System	31 Aug 2020 20:45:40
User entered 'carvedilol'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'No (N)'	(b) (4) Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'hypertension'	(b) (4) Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '25' reason for change: New Information	Peggy Kettle (b) (4)	13 Oct 2020 16:34:53
User entered '1'	Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'mg (mg)' reason for change: New Information	Peggy Kettle (b) (4)	13 Oct 2020 16:34:53
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'twice daily (BID)'	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:14:10
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:35:03
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:35:02
User entered 'un UNK 2014'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '0'	Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
Signature has been broken.	Peggy Kettle (b) (4)	16 Apr 2021 14:05:01
User entered 'No (N)' reason for change: New Information	Peggy Kettle (b) (4)	16 Apr 2021 14:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
Signature has been broken.	(b) (4) Peggy Kettle (b) (4)	16 Apr 2021 14:05:01
User entered '23 Nov 2020' reason for change: New Information	(b) (4) Peggy Kettle (b) (4)	16 Apr 2021 14:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:45:37
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'No (N)'	(b) (4) Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User entered '2'	System	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User entered '1'	System	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:10
User entered '804 (804)'	System	31 Aug 2020 20:45:37

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 20:47:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:47:44
Data point term sent to Coder	System	31 Aug 2020 20:46:41
User entered 'amlodipine'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'hypertension'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 04:13:12
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'added' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:35:42
User entered '10' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:35:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 5 MG, 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:55:13
User entered '1'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:35:35
	(b) (4)	
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'twice daily (BID)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:14:27
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:35:55
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:55:22
User entered 'un UNK 2014'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:46:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 20:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:49:34
Data point term sent to Coder	System	31 Aug 2020 20:47:42
User entered 'lisinopril'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'hypertension'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 04:13:37
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'added' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:36:30
User entered '30' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:36:24
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:55:54
User entered '1'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:36:24
	(b) (4)	
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:15:12
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH start date corrected' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:36:41
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:55:46
User entered 'un UNK 2019'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:46:53
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:46:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:25:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:25:30
Data point term sent to Coder Coding entries removed.	System Peggy Kettle (b) (4)	05 Jan 2021 19:25:06 05 Jan 2021 19:25:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:49:34
Data point term sent to Coder User entered 'potassium'	System Laila Hussaini (b) (4)	31 Aug 2020 20:47:43 31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH#5 Hypokalemia). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:30:06
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH#5 Hypokalemia). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'corrected' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	05 Jan 2021 19:25:13
User entered 'No (N)' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	05 Jan 2021 19:25:03
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH#5 Hypokalemia). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:47:57
User closed query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:28:41
Query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'changed to prophylaxis per query request' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	17 Nov 2020 16:18:12
User entered 'Yes (Y)' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	17 Nov 2020 16:17:51
User opened query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:12:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'hypokalemia' reason for change: Per Query Resolution	(b) (4)	05 Jan 2021 19:25:03
User entered 'general health'	Peggy Kettle (b) (4)	31 Aug 2020 20:47:38
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '10' reason for change: New Information	(b) (4) Peggy Kettle (b) (4)	13 Oct 2020 16:37:31
User entered '1'	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:47:38
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Other (OTHER)' reason for change:	(b) (4)	
New Information	Peggy Kettle (b) (4)	13 Oct 2020 16:37:31
User entered 'tablet (TABLET)'	(b) (4)	
	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'meq' reason for change: New Information	Peggy Kettle (b) (4)	13 Oct 2020 16:37:31
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'un UNK 2018'	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '0'	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
Signature has been broken.	(b) (4) Peggy Kettle (b) (4)	16 Apr 2021 14:06:10
User entered 'No (N)' reason for change: New Information	(b) (4) Peggy Kettle (b) (4)	16 Apr 2021 14:06:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Yes (Y)'	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
Signature has been broken.	(b) (4) Peggy Kettle (b) (4)	16 Apr 2021 14:06:10
User entered '23 Nov 2020' reason for change: New Information	(b) (4) Peggy Kettle (b) (4)	16 Apr 2021 14:06:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Laila Hussaini (b) (4)	31 Aug 2020 20:47:38
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User entered '1'	System	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User entered '1'	System	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:16
User entered '804 (804)'	System	31 Aug 2020 20:47:38

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Oct 2020 16:40:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:40:26
Data point term sent to Coder	System	13 Oct 2020 16:38:49
Coding entries removed.	Peggy Kettle (b) (4)	13 Oct 2020 16:38:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 07:37:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 07:37:45
Data point term sent to Coder	System	03 Sep 2020 00:25:47
Coding entries removed.	Peggy Kettle (b) (4)	03 Sep 2020 00:25:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:49:34
Data point term sent to Coder	System	31 Aug 2020 20:48:44
User entered 'multi-vitamin'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'changed to prophylaxis per query request' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:28:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	17 Nov 2020 16:18:50
User opened query 'Per DM CLR: Indication = GENERAL HEALTH, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	17 Nov 2020 16:18:22
	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 09:12:45
	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 05:16:56
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'data entry error, for general health' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:38:28
User entered 'general health' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:38:09
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:50:03
User entered 'HYPOKALEMIA' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:25:30
User entered 'general health'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '1'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 05:37:02
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'data entry error, for general health' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:38:39
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:50:35
User entered 'un UNK 2014'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:10
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:48:10

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Sep 2020 02:18:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:18:34
Data point term sent to Coder	System	31 Aug 2020 20:49:45
User entered 'Calcium'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'chronic kidney failure'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 600 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 04:11:43
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 600 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'added' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:39:33
User entered '1334' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:39:28
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 600 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:35:19
User entered '2'	Laila Hussaini (b) (4) (b) (4)	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:39:28
	(b) (4)	
User entered 'tablet (TABLET)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'three times daily (TID)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'un UNK 2019'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	31 Aug 2020 20:48:54
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
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)	03 Sep 2020 06:06:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:06:34
Data point term sent to Coder	System	03 Sep 2020 00:27:49
User entered 'FUROSEMIDE (lasix)'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'chronic kidney failure'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 04:13:51
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'added' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:40:07
User entered '120' reason for change: Per Query Resolution	Peggy Kettle (b) (4) (b) (4)	13 Oct 2020 16:40:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:49:44
User entered '3'	Peggy Kettle (b) (4) (b) (4)	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Peggy Kettle (b) (4)	13 Oct 2020 16:40:01
	(b) (4)	
User entered 'tablet (TABLET)'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'twice daily (BID)'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'un UNK 2018'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 00:28:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 00:28:01
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	03 Sep 2020 00:28:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 00:27:26
User entered empty.	Peggy Kettle (b) (4)	03 Sep 2020 00:27:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 00:27:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Nov 2020 17:21:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 17:21:52
Data point term sent to Coder	System	19 Oct 2020 12:22:15
User entered 'Tums'	Peggy Kettle (b) (4) (b) (4)	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Chronic kidney failure'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '1000'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'mg (mg)'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'three times daily (TID)'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'un UNK 2017'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'No (N)'	Peggy Kettle (b) (4)	19 Oct 2020 12:21:26
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 12:21:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Jan 2021 19:27:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:27:36
Data point term sent to Coder	System	05 Jan 2021 19:27:08
User entered 'vitamin D3'	Peggy Kettle (b) (4) (b) (4)	05 Jan 2021 19:26:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'general health'	(b) (4) Peggy Kettle (b) (4) (b) (4)	05 Jan 2021 19:26:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '50'	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'ug (ug)'	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'once daily (QD)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	05 Jan 2021 19:26:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '5 Jan 2021'	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered '0'	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
User entered empty.	Peggy Kettle (b) (4)	05 Jan 2021 19:26:39
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 06:00:31
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'changed' (Site from DM).	Peggy Kettle (b) (4) (b) (4)	08 Feb 2021 13:40:41
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	08 Feb 2021 13:40:23
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 03:56:58
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	05 Jan 2021 19:26:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 19:26:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 19:26:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 19:26:39

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:14:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:12:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:12:42
Data point term sent to Coder	System	04 Mar 2021 20:20:34
User entered 'BISACODYL'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:14:44
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:14:46
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:14:51
User entered '10'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:14:55
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:14:57
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:14:58
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:00
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:03
User entered 'Rectal (RECTAL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:07
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:08
User entered '23 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:11
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:13
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:15
User entered '23 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:18
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User entered empty.	System	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User entered empty.	System	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:46
User entered empty.	System	04 Mar 2021 20:20:34

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:23:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:23:02
Data point term sent to Coder	System	04 Mar 2021 20:22:36
User entered 'ACETAMINOPHEN'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:36
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:39
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:41
User entered '975'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:43
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:46
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:48
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:49
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:52
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:54
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:56
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:15:57
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:00
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:22:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 20:22:06
User entered 'No (N)' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:06
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:22:01
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:02
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:04
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User entered empty.	System	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User entered empty.	System	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:51
User entered empty.	System	04 Mar 2021 20:22:01

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:39:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:39:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:24:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:24:04
Data point term sent to Coder	System	04 Mar 2021 20:23:37
User entered 'ACETAMINOPHEN'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:26
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:27
User entered 'KIDENY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:32
User entered '1000'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:37
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:39
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:40
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:42
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:46
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:48
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:50
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:51
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:53
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:55
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:16:57
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User entered empty.	System	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User entered empty.	System	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:57
User entered empty.	System	04 Mar 2021 20:23:11

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: VECURONIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
Data point term sent to Coder	System	04 Mar 2021 20:24:38
User entered 'VECURONIUM'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:14
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:16
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:19
User entered '10'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:23
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:25
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:26
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:29
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:31
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:33
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:35
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:37
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:39
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:40
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:17:42
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User entered empty.	System	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User entered empty.	System	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:05
User entered empty.	System	04 Mar 2021 20:24:20

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:11
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:51:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:51:53
Data point term sent to Coder	System	04 Mar 2021 20:25:40
User entered 'SUGAMMADEX'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:12
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:15
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:20
User entered '350'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:21
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:23
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:26
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:27
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:29
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:31
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:32
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:48
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:52
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:54
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:18:55
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User entered empty.	System	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User entered empty.	System	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:12
User entered empty.	System	04 Mar 2021 20:25:32

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:02
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:52:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:52:43
Data point term sent to Coder	System	04 Mar 2021 20:27:46
User entered 'SUGAMMADEX'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:04
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:05
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:09
User entered '200'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:11
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:12
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:13
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:27:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 20:27:06
User entered 'once (ONCE)' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:27:06
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:26:57
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:15
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:18
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:20
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:22
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:24
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:26
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:28
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:29
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User entered empty.	System	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User entered empty.	System	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:19
User entered empty.	System	04 Mar 2021 20:26:57

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:00:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:00:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:19:36
Data point term sent to Coder	System	04 Mar 2021 20:28:51
User entered 'ROCURONIUM'	Peggy Kettle (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:38
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:40
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:42
User entered '50'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:44
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:46
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:48
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:50
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:52
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:54
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:55
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:19:56
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:00
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:02
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:03
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User entered empty.	System	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User entered empty.	System	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:30
User entered empty.	System	04 Mar 2021 20:28:08

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:00:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 08:00:04
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:20:11
Data point term sent to Coder	System	04 Mar 2021 20:37:20
User entered 'ROCURONIUM'	Peggy Kettle (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:18
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:20
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:22
User entered '30-70'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:26
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:28
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:31
User entered 'as needed (PRN)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:33
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:35
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:37
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:40
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:42
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:43
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:45
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:47
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User entered empty.	System	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User entered empty.	System	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:37
User entered empty.	System	04 Mar 2021 20:36:43

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:20:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:47:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:47:46
Data point term sent to Coder	System	04 Mar 2021 20:38:35
User entered 'PROPOFOL (10MG/ML)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:00
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:01
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:04
User entered '50-150'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:07
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:10
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:11
User entered 'as needed (PRN)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:14
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:16
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:17
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:20
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:21
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:23
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:26
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:21:27
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User entered empty.	System	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User entered empty.	System	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:48
User entered empty.	System	04 Mar 2021 20:38:22

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:49:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:49:46
Data point term sent to Coder	System	04 Mar 2021 20:41:43
User entered 'PROPOFOL'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:18
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:20
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:22
User entered '50-150'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:25
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:26
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:28
User entered 'as needed (PRN)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:30
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:31
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:34
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:36
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:37
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:40
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:42
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:22:44
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User entered empty.	System	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User entered empty.	System	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:05
User entered empty.	System	04 Mar 2021 20:41:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
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 CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:10:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:10:57
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:23:43
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: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:02:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:02:51
Data point term sent to Coder	System	04 Mar 2021 20:42:45
User entered 'SODIUM CHOLORIDE'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:23:45
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:23:49
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:23:55
User entered '700'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:23:59
User entered 'mL (mL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:00
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:02
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:04
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:07
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:08
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:10
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:13
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:15
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:16
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:24:18
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User entered empty.	System	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User entered empty.	System	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:12
User entered empty.	System	04 Mar 2021 20:42:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
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)	19 Apr 2021 10:09:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:09:35
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:14:35
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: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:33:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:33:57
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:25:03
Data point term sent to Coder	System	04 Mar 2021 20:44:48
User entered 'SODIUM BICARBONATE'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:04
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:06
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:09
User entered '50'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:11
User entered 'Other (OTHER)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:13
User entered 'mEq'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:14
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:45:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 20:45:33
User entered 'once (ONCE)' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:45:33
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:44:40
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:18
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:20
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:22
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:23
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:25
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:28
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:30
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:32
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User entered empty.	System	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User entered empty.	System	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:19
User entered empty.	System	04 Mar 2021 20:44:40

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
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)	08 Mar 2021 07:42:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:42:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:25:49
Data point term sent to Coder	System	04 Mar 2021 20:49:53
User entered 'MIRALX'	Peggy Kettle (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:25:55
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:04
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:07
User entered '17'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:20
User entered 'g (g)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:22
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:23
User entered 'once daily (QD)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:25
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:28
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:43
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:48
User entered '23 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:51
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:26:52
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:28:56
User entered '01 Dec 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:28:58
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User entered '1'	System	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User entered '1'	System	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:24
User entered '804 (804)'	System	04 Mar 2021 20:48:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Mar 2021 12:06:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:06:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:29:09
Data point term sent to Coder	System	04 Mar 2021 20:50:56
User entered 'OXYCODONE'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:11
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:14
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:17
User entered '5'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:18
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:21
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:24
User entered 'as needed (PRN)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:26
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:27
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:30
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:32
User entered '23 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:33
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:36
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:38
User entered '30 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:41
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User entered empty.	System	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User entered empty.	System	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:33
User entered empty.	System	04 Mar 2021 20:50:36

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 08:08:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 08:08:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:29:48
Data point term sent to Coder	System	04 Mar 2021 20:53:08
User entered 'ONDANSETRON'	Peggy Kettle (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:01
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:05
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:07
User entered '4'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:09
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:11
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:13
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:16
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:17
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:19
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:20
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:23
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:25
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:27
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:28
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User entered empty.	System	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User entered empty.	System	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:38
User entered empty.	System	04 Mar 2021 20:52:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 11:39:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:39:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:30:33
Data point term sent to Coder	System	04 Mar 2021 20:54:09
User entered 'NOREPINEPHRINE'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:34
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:36
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
User entered '1.6989'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:51
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:54
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:55
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:57
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:00
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:06
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:07
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:10
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:11
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:14
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:16
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User entered empty.	System	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User entered empty.	System	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:44
User entered empty.	System	04 Mar 2021 20:54:05

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: NALOXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 14:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:34:43
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:31:43
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:31:41
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:31:39
Data point term sent to Coder	System	04 Mar 2021 20:55:13
User entered 'NALOXONE'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:45
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:47
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:50
User entered '0.04'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:51
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:53
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:54
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:56
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:31:59
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:00
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:03
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:04
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:10
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:12
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:13
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User entered empty.	System	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User entered empty.	System	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:49
User entered empty.	System	04 Mar 2021 20:55:06

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:44:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:44:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:32:23
Data point term sent to Coder	System	04 Mar 2021 20:56:18
User entered 'MIDAZOLAM (1MG/ML)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:31
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:35
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:37
User entered '2'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:39
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:40
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:43
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:45
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:46
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:48
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:50
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:52
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:54
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:56
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:32:57
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User entered empty.	System	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User entered empty.	System	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:05
User entered empty.	System	04 Mar 2021 20:56:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:44:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:44:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:33:08
Data point term sent to Coder	System	04 Mar 2021 21:00:25
User entered 'MIDAZOLAM (1MG/ML)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:10
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:11
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:13
User entered 'l'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:16
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:17
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:27
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:30
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:32
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:34
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:37
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:38
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:41
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:42
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:45
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User entered empty.	System	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User entered empty.	System	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:11
User entered empty.	System	04 Mar 2021 20:59:44

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:42
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:33:53
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)	05 Mar 2021 05:42:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:42:46
Data point term sent to Coder	System	04 Mar 2021 21:01:26
User entered 'MAGNESIUM SULFATE'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:58
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:33:59
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:07
User entered '4'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:09
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:10
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:12
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:15
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:17
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:19
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:21
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:22
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:24
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:27
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:29
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User entered empty.	System	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User entered empty.	System	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:16
User entered empty.	System	04 Mar 2021 21:00:50

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:28
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)	05 Mar 2021 05:43:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:43:46
Data point term sent to Coder	System	04 Mar 2021 21:02:36
User entered 'LIDOCAINE 2%'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:30
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:32
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:34
User entered '100'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:35
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:38
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:40
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:41
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:43
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:44
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:47
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:49
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:51
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:53
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:55
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User entered empty.	System	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User entered empty.	System	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:22
User entered empty.	System	04 Mar 2021 21:02:03

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:00
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)	05 Mar 2021 05:43:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:43:47
Data point term sent to Coder	System	04 Mar 2021 21:03:38
User entered 'LIDOCAINE 2%'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:02
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:06
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:08
User entered '100'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:10
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:12
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:14
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:16
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:18
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:21
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:23
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:25
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:27
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:29
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:31
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User entered empty.	System	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User entered empty.	System	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:28
User entered empty.	System	04 Mar 2021 21:03:04

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	17 Mar 2021 11:05:48
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:36:43
Data point term sent to Coder	System	04 Mar 2021 21:04:38
User entered 'LACTATE RINGERS'	Peggy Kettle (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:48
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:50
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:52
User entered '500'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:36:58
User entered 'mL (mL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:00
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:01
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:03
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:04
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:24
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:25
User entered '19 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:27
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:28
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:30
User entered '19 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:37:32
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User entered empty.	System	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User entered empty.	System	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:36
User entered empty.	System	04 Mar 2021 21:03:54

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
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, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:42:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 14:42:57
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:38:19
Data point term sent to Coder	System	04 Mar 2021 21:05:41
User entered 'INSULIN REGULAR'	Peggy Kettle (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:38:33
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:38:35
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:38:37
User entered '1.6-10'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:38:39
User entered 'IU (IU)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:38:40
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:38:59
User entered 'as needed (PRN)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:02
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:05
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:06
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:09
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:11
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:13
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:21
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:23
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User entered empty.	System	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User entered empty.	System	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:03:43
User entered empty.	System	04 Mar 2021 21:05:16

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Mar 2021 21:24:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 21:24:53
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:39:31
Data point term sent to Coder	System	04 Mar 2021 21:06:42
User entered 'HYDROMORPHONE (2MG/ML)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:52
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:57
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:00
User entered '0.5'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:03
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:14
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:16
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:26
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:28
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:30
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:31
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:34
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:36
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:38
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:40:40
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User entered empty.	System	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User entered empty.	System	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:10
User entered empty.	System	04 Mar 2021 21:06:31

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Mar 2021 21:12:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 21:12:59
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:41:00
Data point term sent to Coder	System	04 Mar 2021 21:07:45
User entered 'HYDROMORPHONE (2MG/ML)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:09
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:11
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:14
User entered '0.5'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:16
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:17
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:20
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:22
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:24
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:26
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:27
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:29
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:35
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:40
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User entered empty.	System	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User entered empty.	System	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:15
User entered empty.	System	04 Mar 2021 21:07:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 07:59:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 07:59:03
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:41:53
Data point term sent to Coder	System	04 Mar 2021 21:08:46
User entered 'HYDRALAZINE'	Peggy Kettle (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:42:02
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:42:52
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:06
User entered '10'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:13
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:15
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:21
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:23
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:25
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:29
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:31
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:33
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:34
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:36
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:43:39
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User entered empty.	System	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User entered empty.	System	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:21
User entered empty.	System	04 Mar 2021 21:08:28

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:11:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:11:01
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:44:14
Data point term sent to Coder	System	04 Mar 2021 21:10:49
User entered 'FENTANYL (50MCG/ML)' reason for change: Data Entry Error	Peggy Kettle (b) (4)	04 Mar 2021 21:09:58
Data point term sent to Coder	System	04 Mar 2021 21:09:47
User entered 'FENTANYL'	Peggy Kettle (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:18
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:34
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:36
User entered '100'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:37
User entered 'ug (ug)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:39
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:40
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:42
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:45
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:50
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:52
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:53
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:56
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:57
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:59
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User entered empty.	System	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User entered empty.	System	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:26
User entered empty.	System	04 Mar 2021 21:09:27

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:12:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:12:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:45:04
Data point term sent to Coder	System	04 Mar 2021 21:11:52
User entered 'FENTANYL (50MCG/ML)'	Peggy Kettle (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:45:07
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:45:09
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:45:18
User entered '100'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:45:20
User entered 'ug (ug)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:45:22
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:45:24
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:45:26
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:29
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:31
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:33
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:35
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:38
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:40
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:41
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User entered empty.	System	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User entered empty.	System	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:33
User entered empty.	System	04 Mar 2021 21:11:14

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: EPINEPHRINE;LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 07:34:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:34:53
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:47:52
Data point term sent to Coder	System	04 Mar 2021 21:13:56
User entered 'EPINEPHRINE-LIDOCAINE (LIDOCAINE 1% ePI 1:100,000)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:53
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:56
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:47:58
User entered '10'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:00
User entered 'mL (mL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:03
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:11
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:18
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:19
User entered 'Subcutaneous (SUBCUTANEOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:21
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:24
User entered '19 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:26
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:28
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:30
User entered '19 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:32
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User entered empty.	System	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User entered empty.	System	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:01
User entered empty.	System	04 Mar 2021 21:12:58

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
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: ELECTROLYTES NOS, PRODUCTSYNONYM: PLASMA-LYTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:43:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:43:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:48:55
Data point term sent to Coder	System	04 Mar 2021 21:13:56
User entered 'PLASMA-LYTE'	Peggy Kettle (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:48:58
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:00
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:03
User entered '1000'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:26
User entered 'mL (mL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:28
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:30
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:32
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:35
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:37
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:39
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:40
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:43
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:45
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:47
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User entered empty.	System	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User entered empty.	System	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:07
User entered empty.	System	04 Mar 2021 21:13:55

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
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: ELECTROLYTES NOS, PRODUCTSYNONYM: PLASMA-LYTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:59:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:59:31
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:49:52
Data point term sent to Coder	System	04 Mar 2021 21:14:57
User entered 'PLASMA-LYTE'	Peggy Kettle (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:54
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:56
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:58
User entered '400-1000'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:49:59
User entered 'mL (mL)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:01
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:04
User entered 'as needed (PRN)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:07
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:37
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:39
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:41
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:43
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:44
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:46
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:49
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User entered empty.	System	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User entered empty.	System	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:14
User entered empty.	System	04 Mar 2021 21:14:53

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:57:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:57:43
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:51:10
Data point term sent to Coder	System	04 Mar 2021 21:16:58
User entered 'DEXTROSE (50%/50ML)'	Peggy Kettle (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:11
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:14
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:15
User entered '25'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:17
User entered 'g (g)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:23
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:28
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:30
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:31
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:33
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:36
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:37
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:38
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:40
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:42
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User entered empty.	System	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User entered empty.	System	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:27
User entered empty.	System	04 Mar 2021 21:16:33

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:51:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: DESMOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:18:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:18:50
Data point term sent to Coder	System	04 Mar 2021 21:20:06
User entered 'DESMOPRESSIN'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:05
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:07
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:12
User entered '24'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:13
User entered 'ug (ug)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:15
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:17
User entered 'other (OTHER)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:19
User entered 'TWICE'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:20
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:22
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:24
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:26
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:28
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:30
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:32
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User entered empty.	System	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User entered empty.	System	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:39
User entered empty.	System	04 Mar 2021 21:19:26

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:10:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:10:46
Data point term sent to Coder	System	04 Mar 2021 21:21:07
User entered 'CEFAZOLIN'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:54
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:56
User entered 'KIDNEY CANCER'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:52:59
User entered '2'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:53:01
User entered 'g (g)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:53:02
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:47:24
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Un-verified.	(b) (4) Peggy Kettle (b) (4)	08 Mar 2021 14:02:29
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4) Peggy Kettle (b) (4)	08 Mar 2021 14:02:29
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:53:04
User entered 'other (OTHER)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User closed query 'per medication record= x 1, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:47:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:47:27
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
Query 'per medication record= x 1, please verify' answered with 'VERIFIED, ONLY GIVEN ONCE' (Site from CRA).	Peggy Kettle (b) (4)	08 Mar 2021 14:02:44
User entered empty; reason for change Data Entry Error	Peggy Kettle (b) (4)	08 Mar 2021 14:02:29
User opened query 'per medication record= x 1, please verify' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 15:55:15
User entered 'TWICE'	Peggy Kettle (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:05
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:08
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:10
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:12
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:14
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:15
User entered '18 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:56:17
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User entered empty.	System	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User entered empty.	System	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:45
User entered empty.	System	04 Mar 2021 21:20:47

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
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: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 23:54:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:56:58
Data point term sent to Coder	System	04 Mar 2021 21:22:09
User entered 'CALCIUM GLUCONATE'	Peggy Kettle (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:02
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:04
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:06
User entered '1000-2000'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:08
User entered 'ug (ug)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:12
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:15
User entered 'as needed (PRN)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:19
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:20
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:23
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:26
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:27
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:30
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:32
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:33
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User entered empty.	System	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User entered empty.	System	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:52
User entered empty.	System	04 Mar 2021 21:21:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: OTHER SYSTEMIC HEMOSTATICS, PRODUCT: DESMOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:10:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:10:00
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:57:39
Data point term sent to Coder	System	04 Mar 2021 21:23:09
User entered 'DESMOOPRESSIN'	Peggy Kettle (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:40
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:42
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:46
User entered '24'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:49
User entered 'ug (ug)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:51
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:52
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:54
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:56
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:57:58
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:00
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:02
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:03
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:05
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:07
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User entered empty.	System	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User entered empty.	System	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:05:59
User entered empty.	System	04 Mar 2021 21:22:49

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:10:45
Data point term sent to Coder	System	04 Mar 2021 21:24:12
User entered 'CEFAZOLIN'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:15
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:17
User entered 'RETROPERITONEAL BLEED'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:20
User entered '2'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:23
User entered 'g (g)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:24
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:26
User entered 'once (ONCE)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:29
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:32
User entered 'Intravenous (INTRAVENOUS)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:33
User entered empty.	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:35
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:37
User entered '0'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:40
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:41
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:58:43
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User entered empty.	System	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User entered empty.	System	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:06:05
User entered empty.	System	04 Mar 2021 21:23:29

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:47
Data point term sent to Coder	System	16 Apr 2021 14:12:08
User entered 'CARVEDILOL'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered 'HYPERTENSION'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered '50'	Peggy Kettle (b) (4)	16 Apr 2021 14:11:17
	(b) (4)	

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered 'mg (mg)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:11:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 14:11:32
User entered 'twice daily (BID)' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:32
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:11:17
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered '23 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered '0'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:48:21
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 14:11:32
User entered empty.	System	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:11:32
User entered empty.	System	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 14:11:32
User entered empty.	System	16 Apr 2021 14:11:17

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:50
Data point term sent to Coder	System	16 Apr 2021 14:13:09
User entered 'POTASSIUM'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'HYPOKALEMIA'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered '20'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'Other (OTHER)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'mEq'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'once daily (QD)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'Oral (ORAL)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered '23 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered '0'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered empty.	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:49:20
User entered 'No (N)'	Peggy Kettle (b) (4) (b) (4)	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 08:12:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 14:13:00

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:12:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:53
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:49:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:27
User closed query 'source also = 20Nov20, transfusion of Platelets and transfusion of PRBC, please verify and update' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:20:10
Query 'source also = 20Nov20, transfusion of Platelets and transfusion of PRBC, please verify and update' answered with 'ADDED TRANSFUSIONS' (Site from CRA).	Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:18:47
User opened query 'source also = 20Nov20, transfusion of Platelets and transfusion of PRBC, please verify and update' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:16:29
User entered 'Yes (Y)'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 17:41:38

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:18

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:14:35
User entered '18 Nov 2020' reason for change: Data Entry Error	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:00:56
User entered '17 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 17:43:01

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:14:37
User entered 'RIGHT RADICAL NEPHRECTOMY'	Peggy Kettle (b) (4)	01 Dec 2020 18:00:56
reason for change: Data Entry Error	(b) (4)	
User entered 'right kidney removal'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 17:43:01

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:14:38
User entered 'Adverse Event (AE)'	Peggy Kettle (b) (4)	01 Dec 2020 17:43:01
	(b) (4)	

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:12:18

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:14:41
User entered empty.	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 17:43:01

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:15:13
User entered '20 Nov 2020'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:12:11

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:42:14
User closed query 'Please confirm added to con procedure log' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:42:12
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
Query 'Please confirm added to con procedure log' answered with 'ADDED TO CON PROCEDURE LOG' (Site from CRA).	(b) (4)	
	Peggy Kettle (b) (4)	08 Mar 2021 14:13:56
	(b) (4)	
User opened query 'Please confirm added to con procedure log' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:15:10
User entered 'EXPLORATORY LAP: EVACUATION OF HEMATOMA, CLIP PLACEMENT NEAR RENAL HILUM'	Peggy Kettle (b) (4)	01 Dec 2020 18:12:11
	(b) (4)	

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:15:15
User entered 'Adverse Event (AE)'	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:12:11

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:12:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:46
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:15:18
User entered empty.	Peggy Kettle (b) (4) (b) (4)	01 Dec 2020 18:12:11

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:56
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '20 Nov 2020'	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:16:45

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:58
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'TRANSFUSION OF PLASMA'	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:16:45

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:56:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Adverse Event (AE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:16:45

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:12:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:56:34
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:16:45

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:56:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered '20 Nov 2020'	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:17:10

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:56:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'TRANSFUSION OF RBC'S'	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:17:10

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:56:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered 'Adverse Event (AE)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:17:10

US3532192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:12:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:56:37
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
User entered empty.	(b) (4) Peggy Kettle (b) (4) (b) (4)	08 Mar 2021 14:17:10

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered	System	13 Nov 2020 13:17:13
'USA-US077-2020-MRNA-1273-P301000012'		

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
User entered '13/Nov/2020 08:17'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:41
User entered '02/Dec/2020 15:12'	System	02 Dec 2020 15:12:07

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:36:57
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 15:12:07

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
User entered '04/Dec/2020 15:37'	System	04 Dec 2020 15:37:28

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 15:37:28

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:41
User entered '08/Dec/2020 15:40'	System	08 Dec 2020 20:40:42

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:31:39
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 20:40:42

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:41
User entered '02/Feb/2021 09:31'	System	02 Feb 2021 14:31:15

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:31:39
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 14:31:15

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:47:11
User entered '05/Mar/2021 12:34'	System	05 Mar 2021 17:34:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:47:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 17:34:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'USA-US077-2020-MRNA-1273-P301000012'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:46:42
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:18:47
Un-reviewed for Safety.	System	08 Mar 2021 13:42:42
DataPoint Un-verified.	System	08 Mar 2021 13:42:42
User entered 'No (N)'	System	08 Mar 2021 13:42:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:40:31
Un-reviewed for Safety.	System	08 Dec 2020 20:40:24
User entered 'Yes (Y)'	System	08 Dec 2020 20:40:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'No (N)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Yes (Y)'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Evan'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered 'Anderson'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '2015 Uppergate Drive'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered 'Atlanta'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
	(b) (4), (b) (6)	
User entered 'GA'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:41
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:17:34
User entered '30323'	System	13 Nov 2020 13:17:13

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	05 Mar 2021 16:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:11:55
User entered 'US'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	09 Mar 2021 14:19:01
User entered '6'	System	05 Mar 2021 17:34:14
User entered '5'	System	02 Feb 2021 14:31:15
User entered '4'	System	08 Dec 2020 20:40:42
User entered '3'	System	04 Dec 2020 15:37:28
User entered '2'	System	02 Dec 2020 15:12:07
User entered '1'	System	13 Nov 2020 13:17:40

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:47:15
User entered '09/Mar/2021 14:19'	System	09 Mar 2021 14:19:01

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 15:47:15
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 14:19:01

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered	System	02 Dec 2020 15:41:14
'USA-US077-2020-MRNA-1273-P301000014'		

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
Un-reviewed for Safety.	System	03 Dec 2020 17:48:55
User entered 'Yes (Y)'	System	03 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
Un-reviewed for Safety.	System	03 Dec 2020 17:48:55
User entered 'Yes (Y)'	System	03 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Evan'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Anderson'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered '2015 Uppergate Drive'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Atlanta'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'GA'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered '30323'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
User entered 'US'	System	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Dec 2020 15:59:04
User entered '1'	System	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered	System	02 Dec 2020 15:41:14
'USA-US077-2020-MRNA-1273-P301000014'		

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
Un-reviewed for Safety.	System	03 Dec 2020 17:48:55
User entered 'Yes (Y)'	System	03 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
Un-reviewed for Safety.	System	03 Dec 2020 17:48:55
User entered 'Yes (Y)'	System	03 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Evan'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Anderson'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered '2015 Uppergate Drive'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Atlanta'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'GA'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered '30323'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
User entered 'US'	System	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Dec 2020 15:59:04
User entered '1'	System	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:10:54
User entered '02/Dec/2020 15:41'	System	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered	System	02 Dec 2020 15:41:14
'USA-US077-2020-MRNA-1273-P301000014'		

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
Un-reviewed for Safety.	System	03 Dec 2020 17:48:55
User entered 'Yes (Y)'	System	03 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
Un-reviewed for Safety.	System	03 Dec 2020 17:48:55
User entered 'Yes (Y)'	System	03 Dec 2020 17:48:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'No (N)'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Evan'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Anderson'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered '2015 Uppergate Drive'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'Atlanta'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered 'GA'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:41:32
User entered '30323'	System	02 Dec 2020 15:41:14

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 15:58:37
User entered 'US'	System	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 08:12:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Dec 2020 15:59:04
User entered '1'	System	02 Dec 2020 15:41:39

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:12:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
User entered '04/Dec/2020 15:59'	System	04 Dec 2020 15:59:04

US3532192

Folder: SAE USA-US077-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:12:18

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.	Evan Anderson (b) (4)	02 Apr 2021 20:14:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:10:54
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 15:59:04