

US3642024 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:09:46

All time stamps listed in this document are displayed in GMT

US3642024

Form: Participant Creation

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

[Participant ID](#)

US3642024

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

US3642024

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:23:23

Generated On: 10 Jun 2021 09:09:46

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

Condition	DANDRUFF
Start date (dd MMM yyyy)	24 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	17 OCT 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	28 MAR 2007
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)	MAR 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

Condition	ATRIAL ECTOPY
Start date (dd MMM yyyy)	25 FEB 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

Condition	INSOMNIA
Start date (dd MMM yyyy)	02 MAY 2015
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)	MAY 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 02:23:19

Generated On: 10 Jun 2021 09:09:46

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:23:24

Generated On: 10 Jun 2021 09:09:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:12 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 14:12
Height (<i>xxx.x</i>)	175.5 cm
Weight (<i>xxx.x</i>)	77.3 kg
BMI (<i>xxx.x</i>)	25.09720 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 31 Aug 2020 23:54:28

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 31 Aug 2020 23:54:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:23:25

Generated On: 10 Jun 2021 09:09:46

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188600

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) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

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) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

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)	27 AUG 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 14:12
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

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)	27 AUG 2020
Time of assessment (00:00-23:59)	16:47 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 16:47
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:23:25

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 31 Aug 2020 23:54:28

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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) 27 AUG 2020

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

Treatment Date and Time (derived) 27 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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Aug 2020 23:54:27

Generated On: 10 Jun 2021 09:09:46

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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:13	27 AUG 2020 15:13
Nasopharyngeal Swab 2	No		

US3642024

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 27 AUG 2020 16:18

PC Open Date & Time 27 AUG 2020 16:05

PC Close Date & Time 27 AUG 2020 18:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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	27 AUG 2020 19:34
PC Open Date & Time	27 AUG 2020 19:30
PC Close Date & Time	28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

28 AUG 2020 14:09

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

30 AUG 2020 15:48

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

31 AUG 2020 17:44

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 21:41

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:08

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 17:05

PC Open Date & Time

27 AUG 2020 16:05

PC Close Date & Time

27 AUG 2020 18:35

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 19:34

PC Open Date & Time

27 AUG 2020 19:30

PC Close Date & Time

28 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 10:47

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 15:48

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 17:44

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:41

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 17:17

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 18:21
PC Open Date & Time	27 AUG 2020 16:05
PC Close Date & Time	27 AUG 2020 18:35

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 10:00
PC Open Date & Time	27 AUG 2020 19:30
PC Close Date & Time	28 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 10:47
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 15:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 17:43
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:41
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 17:17
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3642024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:17

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:17

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:14

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:13

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:15

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:14

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 14:20
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	17:08 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 17:08
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

What was the treatment time? (00:00-23:59) 16:34 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 16:34

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

What was the frequency of the study treatment dosing? ONCE

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

US3642024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	15:05 (24 HR)
Collection date and time (derived)	01 OCT 2020 15:05

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:00	01 OCT 2020 15:00
Nasopharyngeal Swab 2	No		

US3642024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

01 OCT 2020 17:06

PC Open Date & Time

01 OCT 2020 16:54

PC Close Date & Time

01 OCT 2020 19:24

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	01 OCT 2020 22:56
PC Open Date & Time	01 OCT 2020 20:19
PC Close Date & Time	02 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

02 OCT 2020 12:34

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 13:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:14

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

05 OCT 2020 22:07

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 17:06

PC Open Date & Time

01 OCT 2020 16:54

PC Close Date & Time

01 OCT 2020 19:24

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 22:56

PC Open Date & Time

01 OCT 2020 20:19

PC Close Date & Time

02 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:33

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 13:36

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:13

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 22:06

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 17:02
PC Open Date & Time	01 OCT 2020 16:54
PC Close Date & Time	01 OCT 2020 19:24

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 22:55
PC Open Date & Time	01 OCT 2020 20:19
PC Close Date & Time	02 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:33
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:36
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:13
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

Yes ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:15

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments 3 ATTEMPTS MADE
UNSUCCESSFUL AND CONTACT
MADE OUT OF WINDOW
10/12/20
ATTEMPT 1 10/9 11:28AM
ATTEMPT 2 10/10 6PM
ATTEMPT 3 10/12 10:50AM
CONTACT MADE 10/12 11AM

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:15

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:15

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments CONTACT MADE OUT OF
WINDOW
If Contact Not Made, please provide Comments ATTEMPT 1 19OCT2020 11:08AM

US3642024

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:15

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:16

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:16

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 13:13
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3642024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	13:35 (24 HR)
Collection date and time (derived)	28 OCT 2020 13:35

US3642024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:59

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 12:50:43

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

05 NOV 2020 10:09:03

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 00:01:53

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 21:57:50

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 11:59:42
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 10:43:47

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 10:08:38

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 10:48:45

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 11:17:00

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 09:58:53

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 00:01:53

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 21:47:16

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 10:23:36

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 13:36:47

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 17:03:31
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 20:57:49

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 FEB 2021 19:02:17

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 FEB 2021 00:02:30

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 14:51:21

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 21:50:47

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 16:38:04

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 15:59:25

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 19:12:43

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 10:40:39

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 14:24:01

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 00:03:24

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 20:23:27

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 257

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

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

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

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

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

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

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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 278

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 292

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 299

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 362

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 376

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 390

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 439

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	13 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 453

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	20 NOV 2021 00:01
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Patient Cloud Close Date & Time	24 NOV 2021 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 474

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 502

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 544

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 586

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642024

Folder: New Safety Follow Up Diary (1)

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	20 AUG 2022 00:01
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Patient Cloud Close Date & Time	24 AUG 2022 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 761

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

Patient Cloud Open Date & Time	22 OCT 2022 00:01
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Patient Cloud Close Date & Time	26 OCT 2022 23:59
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US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3642024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:09:46

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 21:00:06

US3642024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:17

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:17

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 21:15:11

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

CALL MISSED D/T STAFF
ERROR.

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:12

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:23:13

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:12

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:37:21

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:37:21

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 23:25:03

Generated On: 10 Jun 2021 09:09:46

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

Visit date (dd MMM yyyy)	23 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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US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 23:25:03

Generated On: 10 Jun 2021 09:09:46

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) _____

US3642024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 23:25:03

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3642024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 23:25:03

Generated On: 10 Jun 2021 09:09:46

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

Collection date (dd MMM yyyy)	23 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:05 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 MAR 2021 14:05
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US3642024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 23:25:03

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 18:56:42

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 18:56:42

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642024

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642024

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3642024

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:23:10

Generated On: 10 Jun 2021 09:09:46

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

Visit date (dd MMM yyyy)	19 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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US3642024

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 02:10:02

Generated On: 10 Jun 2021 09:09:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	8 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3642024

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:23:11

Generated On: 10 Jun 2021 09:09:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3642024

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:23:11

Generated On: 10 Jun 2021 09:09:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	19 JAN 2021
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 12:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:23:11

Generated On: 10 Jun 2021 09:09:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	19 JAN 2021
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 13:32
Temperature (xxx.x)	97.7 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

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

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:23:08

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3642024

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

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:23:07

Generated On: 10 Jun 2021 09:09:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 12:53 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 12:53

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

US3642024

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:23:08

Generated On: 10 Jun 2021 09:09:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00-23:59)	12:35 (24 HR)
Collection date and time (derived)	19 JAN 2021 12:35

US3642024

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 02:23:02

Generated On: 10 Jun 2021 09:09:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	12:37
Collection Date and Time (derived)	19 JAN 2021 12:37

US3642024

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

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:06

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 18:01:20

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

If Contact Not Made, please provide Comments

MULTIPLE UNSUCCESSFUL
ATTEMPTS MADE TO CONTACT
PT ON 1/26/21, 1/26/21,1/27/21.
EMAIL SENT. PT DID NOT
RETURN CALL.

US3642024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:23:17

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 01:37:20

Generated On: 10 Jun 2021 09:09:46

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

Visit date (dd MMM yyyy)	17 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 01:37:20

Generated On: 10 Jun 2021 09:09:46

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	13:38 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 13:38
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 01:37:20

Generated On: 10 Jun 2021 09:09:46

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 14:58
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3642024

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 01:37:20

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3642024

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Mar 2021 01:37:20

Generated On: 10 Jun 2021 09:09:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 17 FEB 2021

What was the treatment time? (00:00-23:59) 14:27 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 14:27

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

US3642024

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:37:20

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:37:21

Generated On: 10 Jun 2021 09:09:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 MAR 2021

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

Comments CONTACT MADE 01MAR2021

If Contact Not Made, please provide Comments ATTEMPT 1: 24FEB2021 1038 A

ATTEMPT 2: 24FEB2021 1347 P

ATTEMPT 3 24FEB2021 1706 P

NO VM EMAIL SENT

US3642024

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:37:21

Generated On: 10 Jun 2021 09:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642024

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 23:25:02

Generated On: 10 Jun 2021 09:09:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 23:25:03

Generated On: 10 Jun 2021 09:09:46

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) _____

US3642024

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 23:25:02

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3642024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 23:25:02

Generated On: 10 Jun 2021 09:09:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	23 MAR 2021 14:05

US3642024

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID

Adverse event

MOTOR VEHICLE ACCIDENT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

348 of 3118

EAB) (1725)

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

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	

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID	USA-US109-2021-MRNA-1273-P30 1000013
Adverse event	CLOSED FRACTURE OF MULTIPLE RIBS
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)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	25 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

US3642024

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID	USA-US109-2021-MRNA-1273-P30 1000013
Adverse event	HEMOPNEUMOTHORAX RIGHT SIDE
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)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 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) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

Number of Days in ICU	3
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	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	

US3642024

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID

Adverse event

CLOSED FRACTURE OF BODY
OF RIGHT SCAPULA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID

Adverse event

ABRASIONS OF MULTIPLE
SITES (LOCATIONS UNKNOWN)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:21:04

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PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID	
Adverse event	STAGE 3 CHRONIC KIDNEY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:21:04

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PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID

Adverse event

NO BOWEL MOVEMENT FOR 3
DAYS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

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

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:21:04

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PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID	
Adverse event	MAGNESIUM DEFICIENCY
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)	27 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:21:04

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

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

AEID	
Adverse event	NAUSEA
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)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:21:04

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 31 Aug 2020 23:54:28

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 OCT 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 (2)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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 (2)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 AUG 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication NIZORAL 2% SHAMPOO

Prophylaxis Yes ☐
No ☒

Indication DANDRUFF

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JUL 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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Name of Medication MECLOMEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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

EVERY 6 HOURS

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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 AUG 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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	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)	02 MAY 2015	
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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication ZANAFLEX

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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 (6)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication EFFEXOR

Prophylaxis Yes ☐
No ☒

Indication ANXIETY DISORDER

Dose per administration 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 (7)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 MAY 2015	
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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 AUG 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 (9)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication DULCOLAX

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
CONSTIPATION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 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 (11)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 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"/>

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
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 (13)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

Dose per administration 0.25

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

EVERY 2 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 SEP 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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication IPRATROPIUM-ALBUTEROL
0.5-2.5MG/ML NEBULIZER
SOLUTION

Prophylaxis Yes ☐
No ☒

Indication HEMOPNEUMOTHORAX

Dose per administration M

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 (15)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 SEP 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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication HEMOPNEUMOTHORAX, RIB
FRACTURE, SCAPULA
FRACTURE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication LACTULOSE

Prophylaxis Yes ☐
No ☒

Indication NO BOWEL MOVEMENT FOR 3
DAYS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 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 (18)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication LIDOPATCH 3.6-1.25%

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS

Dose per administration 1

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

If dose unit is Other, specify PATCH

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 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 (19)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication LIDOPATCH 3.6-1.25%

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS

Dose per administration 2

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

If dose unit is Other, specify PATCH

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 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"/>

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication LIDOPATCH 3.6-1.25%

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS

Dose per administration 3

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

If dose unit is Other, specify PATCH

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 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 (21)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐
No ☒

Indication MAGNESIUM DEFICIENCY

Dose per administration 296

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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 SEP 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 (22)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication MAGNESIUM DEFICIENCY

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 (22)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 SEP 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 (23)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	25 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 SEP 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 (25)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

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 (25)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
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 (26)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 SEP 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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication GLYCOLAX

Prophylaxis Yes ☐
No ☒

Indication NO BOWEL MOVMENT FOR 3
DAYS

Dose per administration 1

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

If dose unit is Other, specify PACKET

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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 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 (30)

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Name of Medication SENOKOT-S

Prophylaxis Yes ☐
No ☒

Indication NO BOWEL MOVMENT FOR 3
DAYS

Dose per administration 8.6/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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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 type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 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 (31)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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Name of Medication SODIUM CHLORIDE 0.9%
SOLUTION

Prophylaxis Yes ☐
No ☒

Indication HEMOPNEUMOTHORAX,
CLOSED FRACTURE OF
MULTIPLE RIBS, CLOSED
FRACTURE OF BODY OF RIGHT
SCAPULA

Dose per administration 75

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

If dose unit is Other, specify ML/HOUR

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 SEP 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) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication SODIUM CHLORIDE 3%
NEBULIZER SOLUTION

Prophylaxis Yes ☐
No ☒

Indication HEMOPNEUMOTHORAX

Dose per administration 3

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 (32)

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	29 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

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If frequency is Other, specify	
Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>
	Respiratory (Inhalation) <input type="radio"/>
	Intralesional <input type="radio"/>
	Intraperitoneal <input type="radio"/>
	Nasal <input type="radio"/>
	Vaginal <input type="radio"/>
	Rectal <input type="radio"/>
	Intravenous <input checked="" type="radio"/>
	Intravenous Bolus <input type="radio"/>
	Intravenous Drip <input type="radio"/>
	Other <input type="radio"/>
If route of administration is Other, specify	
Start date (dd MMM yyyy)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	
27 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

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Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Transdermal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	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)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	
27 SEP 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) 19 Apr 2021 18:01:18

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Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

Dose per administration 180

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

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If frequency is Other, specify	
Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>
	Respiratory (Inhalation) <input type="radio"/>
	Intralesional <input type="radio"/>
	Intraperitoneal <input type="radio"/>
	Nasal <input type="radio"/>
	Vaginal <input type="radio"/>
	Rectal <input type="radio"/>
	Intravenous <input checked="" type="radio"/>
	Intravenous Bolus <input type="radio"/>
	Intravenous Drip <input type="radio"/>
	Other <input type="radio"/>
If route of administration is Other, specify	
Start date (dd MMM yyyy)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020
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 (36)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

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If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Transdermal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	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)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	
27 SEP 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) 19 Apr 2021 18:01:18

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Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

Dose per administration 12

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

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If frequency is Other, specify	
Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>
	Respiratory (Inhalation) <input type="radio"/>
	Intralesional <input type="radio"/>
	Intraperitoneal <input type="radio"/>
	Nasal <input type="radio"/>
	Vaginal <input type="radio"/>
	Rectal <input type="radio"/>
	Intravenous <input checked="" type="radio"/>
	Intravenous Bolus <input type="radio"/>
	Intravenous Drip <input type="radio"/>
	Other <input type="radio"/>
If route of administration is Other, specify	
Start date (dd MMM yyyy)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 19 Apr 2021 18:01:18

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Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

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 ☐

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Form: Prior/Concomitant Medication and Vaccination (38)

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If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Transdermal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	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)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	
27 SEP 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) 19 Apr 2021 18:01:18

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Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

Dose per administration 2400

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

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If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Transdermal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	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)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	
27 SEP 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"/>

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication SUGAMMADEX

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

Dose per administration 400

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

If dose unit is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Transdermal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	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)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 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"/>

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

Dose per administration 8

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

If dose unit is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify	
Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>
	Respiratory (Inhalation) <input type="radio"/>
	Intralesional <input type="radio"/>
	Intraperitoneal <input type="radio"/>
	Nasal <input type="radio"/>
	Vaginal <input type="radio"/>
	Rectal <input type="radio"/>
	Intravenous <input checked="" type="radio"/>
	Intravenous Bolus <input type="radio"/>
	Intravenous Drip <input type="radio"/>
	Other <input type="radio"/>
If route of administration is Other, specify	
Start date (dd MMM yyyy)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	
27 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input type="radio"/>

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication	LACTATED RINGERS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PLATING OF RIGHT RIBS 3-7 FRACTURES, RIGHT CHEST TUBE PLACEMENT, EVACUATION OF RETAINED HEMOTHORAX, VIDEO-ASSISTED THORACOSCOPIC SURGERY CRYOABLATION OF RIGHT PARASPINAL NERVES 3-9
Dose per administration	7000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Transdermal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	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)	27 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 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"/>

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

Name of Medication SODIUM CHLORIDE 0.9%
INFUSION

Prophylaxis Yes ☐
No ☒

Indication PLATING OF RIGHT RIBS 3-7
FRACTURES, RIGHT CHEST
TUBE PLACEMENT,
EVACUATION OF RETAINED
HEMOTHORAX,
VIDEO-ASSISTED
THORACOSCOPIC SURGERY
CRYOABLATION OF RIGHT
PARASPINAL NERVES 3-9

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 19 Apr 2021 18:01:18

Generated On: 10 Jun 2021 09:09:46

other ☐

If frequency is Other, specify

Route of administration

Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐
Intramuscular ☐
Respiratory (Inhalation) ☐
Intralesional ☐
Intraperitoneal ☐
Nasal ☐
Vaginal ☐
Rectal ☐
Intravenous ☒
Intravenous Bolus ☐
Intravenous Drip ☐
Other ☐

If route of administration is Other, specify

Start date (dd MMM yyyy) 27 SEP 2020

Start date completely unknown False

Ongoing? Yes ☐
No ☒

If not Ongoing, End date (dd MMM yyyy) 27 SEP 2020

Was this medication taken for solicited event? Yes ☐
No ☒

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived) 802 ☐
803 ☐
804 ☐

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Apr 2021 18:01:19

Generated On: 10 Jun 2021 09:09:46

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Apr 2021 18:01:19

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 SEP 2020	VIDEO-ASSISTED THORACOSCOPIC SURGERY CRYOABLATION OF RIGHT PARASPINAL NERVES 3-9	Adverse Event	
27 SEP 2020	PLATING OF RIGHT RIBS 3-7 FRACTURES	Adverse Event	
27 SEP 2020	RIGHT CHEST TUBE PLACEMENT	Adverse Event	
27 SEP 2020	EVACUATION OF RETAINED HEMOTHORAX	Adverse Event	
25 SEP 2020	CHEST X-RAY	Diagnostic	
25 SEP 2020	CT CHEST, ABSOMEN, PELVIS	Diagnostic	
26 SEP 2020	CHEST X-RAY	Diagnostic	
26 SEP 2020	VASCULAR ULT VENOUS DUPLEX LOWER EXTREMEITY COMPLETE BILATERAL	Diagnostic	
27 SEP 2020	CHEST X-RAY	Diagnostic	
28 SEP 2020	CHEST X-RAY	Diagnostic	
29 SEP 2020	CHEST X-RAY	Diagnostic	
30 SEP 2020	CHEST X-RAY	Diagnostic	

US3642024

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3642024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 31 Aug 2020 23:54:28

Generated On: 10 Jun 2021 09:09:46

Date of study discontinuation/completion (<i>dd MMM yyyy</i>)	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death (<i>dd MMM yyyy</i>)	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

SAEID	USA-US109-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

SAEID	USA-US109-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	13/APR/2021 12:55
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

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:21:04

Generated On: 10 Jun 2021 09:09:46

SAEID	USA-US109-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/APR/2021 13:36
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

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 18:01:19

Generated On: 10 Jun 2021 09:09:46

SAEID	USA-US109-2021-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 checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 18:01:19

Generated On: 10 Jun 2021 09:09:46

SAEID	USA-US109-2021-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 checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	
Date of submission (Pre-filled from custom function)	
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

US3642024 (Prod: University of California San Diego)

US3642024

Form: Participant Creation

Generated On: 10 Jun 2021 09:09:46

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:03:33
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'US3642024'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:39:20

US3642024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:28:31
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:04

US3642024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:28:33
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:39:21

US3642024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[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 20:10:28
DataPoint Verified.	(b) (4)	09 Oct 2020 16:28:35
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:04

US3642024

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'SCRN'	System	27 Aug 2020 22:27:04

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:29:50
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:39:22

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:29:52
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '70'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'YEARS'	System	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '70'	System	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:29:54
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Male (M)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:26
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:28
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'l'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:32
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	09 Oct 2020 16:31:37
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:36
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:39
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:43
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:46
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:48
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:23

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:55
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Aug 2020'	System	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2020'	System	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:58
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Amendment 3 (3)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:31:59
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:32:01
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:32:03
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:32:05
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:41

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:32:06
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:39:21

US3642024

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'I'	System	27 Aug 2020 22:27:48

US3642024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		09 Oct 2020 16:32:15
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:27:48

US3642024

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:09:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:33:16
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:19:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:19:09
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:42:54

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:21:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:21:22
Data point term sent to Coder	System	05 Oct 2020 16:20:25
User entered 'hyperlipidemia'	Son Do (b) (4)	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'I'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:26

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:21:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:21:22
Data point term sent to Coder	System	05 Oct 2020 16:20:25
User entered 'back pain'	Son Do (b) (4)	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'I'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:36

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Anxiety disorder, LLT: Anxiety disorder - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:21:21
Data point term sent to Coder	(b) (4)	
User entered 'anxiety disorder'	System	05 Oct 2020 16:20:26
	Son Do (b) (4)	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'I'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	05 Oct 2020 16:19:45

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Scaly conditions, PT: Dandruff, LLT: Dandruff - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Dec 2020 19:12:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 19:12:01
Data point term sent to Coder	System	16 Dec 2020 19:10:39
User entered 'dandruff'	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '24 Jan 2020'	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4) (b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4) (b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	(b) (4) Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4) (b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Jan 2020'	System	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2020'	System	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:10:27
DataPoint activated with code reason code Data required.	Megan Loughran (b) (4)	16 Dec 2020 19:10:04
DataPoint inactivated with code reason code Data not Son Do required.	(b) (4)	05 Oct 2020 16:20:05

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Dec 2020 19:13:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 19:13:00
Data point term sent to Coder	System	16 Dec 2020 19:11:40
User entered 'prostate cancer'	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'un UNK 2010'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'un UNK 2010'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Jan 2010'	System	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2010'	System	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Jan 2010'	System	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2010'	System	16 Dec 2020 19:11:13

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 19:15:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 19:15:56
Data point term sent to Coder	System	16 Dec 2020 19:14:44
User entered 'Benign prostatic hyperplasia'	Megan Loughran (b) (4)	16 Dec 2020 19:14:16
	(b) (4)	

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '17 Oct 2017'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Oct 2017'	System	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2017'	System	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:14:16

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Dec 2020 19:15:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 19:15:57
Data point term sent to Coder	System	16 Dec 2020 19:14:45
User entered 'osteoporosis'	Megan Loughran (b) (4)	16 Dec 2020 19:14:39
	(b) (4)	

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '28 Mar 2007'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Mar 2007'	System	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2007'	System	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:14:39

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular extrasystoles, LLT: Ectopic atrial beats - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 12:20:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 12:20:12
Data point term sent to Coder	System	16 Dec 2020 19:15:45
User entered 'atrial ectopy'	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '25 Feb 2019'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Feb 2019'	System	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2019'	System	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:14:55

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 19:17:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 19:17:02
Data point term sent to Coder	System	16 Dec 2020 19:15:45
User entered 'insomnia'	Megan Loughran (b) (4)	16 Dec 2020 19:15:12
	(b) (4)	

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '02 May 2015'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'May 2015'	System	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2015'	System	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:15:12

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 19:17:02
Data point term sent to Coder	(b) (4)	
User entered 'depression'	System	16 Dec 2020 19:15:46
	Megan Loughran (b) (4)	16 Dec 2020 19:15:26
	(b) (4)	

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'un UNK 2005'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:13:11
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'Jan 2005'	System	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '2005'	System	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:09:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	16 Dec 2020 19:15:26

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:53:16
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:53:20
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:53:31
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '14:12'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '27 Aug 2020 14:12'	System	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:53:55
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '175.5' cm	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08
DataPoint set to visible.	(b) (4) System	27 Aug 2020 22:27:48

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:54:01
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '77.3' kg	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08
DataPoint set to visible.	(b) (4) System	27 Aug 2020 22:27:48

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '25.09720'	System	31 Aug 2020 12:44:08
DataPoint set to visible.	System	27 Aug 2020 22:27:48

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'kg/m2'	System	31 Aug 2020 12:44:08
DataPoint set to visible.	System	27 Aug 2020 22:27:48

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:54:47
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).		06 Oct 2020 03:25:11
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'corrected' (Site from DM).	Son Do (b) (4)	05 Oct 2020 16:22:00
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:21:52
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:04:59
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '98.1' F	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:56:33
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:21:52
User entered empty; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:21:52
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (Oral)'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:56:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:56:41
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:21:52
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '59'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08
	(b) (4)	

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'bpm'	System	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:56:44
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:21:52
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '18'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08
	(b) (4)	

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'breaths/min'	System	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:56:45
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:21:52
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '137'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'mmHg'	System	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:56:47
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:21:52
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '63'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'mmHg'	System	31 Aug 2020 12:44:08

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28

US3642024

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28

US3642024

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:57:00
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:21

US3642024

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 16:57:03
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:21

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:02:58
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

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 20:10:28
DataPoint Verified.		08 Oct 2020 17:03:00
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:03:03
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
	(b) (4)	
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 12:44:51
	(b) (4)	

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

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 20:10:28
DataPoint Verified.	(b) (4)	08 Oct 2020 17:03:05
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

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 20:10:28
DataPoint Verified.		08 Oct 2020 17:03:07
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:03:10
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

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 20:10:28
DataPoint Verified.		08 Oct 2020 17:03:11
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

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 20:10:28
DataPoint Verified.		08 Oct 2020 17:03:14
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[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 20:10:28
DataPoint Verified.		08 Oct 2020 17:03:16
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	08 Oct 2020 17:03:22
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

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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 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:30
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:33
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:36
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:43
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:44
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:48
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:50
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	08 Oct 2020 17:04:53
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'l'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:44:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		08 Oct 2020 17:04:55
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:44:51

US3642024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:05:05
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:04

US3642024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:05:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:04

US3642024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:05:29
DataPoint Un-verified.		08 Oct 2020 17:05:23
DataPoint Verified.		08 Oct 2020 17:05:10
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:04

US3642024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'VISIT1'	System	27 Aug 2020 22:28:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:10:19
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:44:21

US3642024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:05:46
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '188600'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:44:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:07:36
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 21:44:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:09:58
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:10:00
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:55

US3642024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	08 Oct 2020 17:10:02
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:10:04
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:55

US3642024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:10:07
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:28:55

US3642024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:10:10
User entered 'No (N)'	Son Do (b) (4)	05 Oct 2020 16:22:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:21:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:21:44

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:10:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		06 Oct 2020 04:26:56
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'corrected' (Site from DM).	Son Do (b) (4)	05 Oct 2020 16:22:23
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:22:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:22:20
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:04:47
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '175.5' cm	Megan Loughran (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:10:36
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:22:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:22:20
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '77.3' kg	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:10:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		06 Oct 2020 04:26:56
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'corrected' (Site from DM).	Son Do (b) (4)	05 Oct 2020 16:22:23
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:22:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:22:20
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:04:47
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '175.5' cm	Megan Loughran (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:10:36
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:22:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:22:20
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '77.3' kg	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Pre-Dose (PREDOSE)'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:12
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:14
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:16
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '14:12'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '27 Aug 2020 14:12'	System	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:17
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '98.1' F	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	09 Oct 2020 18:07:19
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (Oral)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:21
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:22
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '59'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'bpm'	System	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	09 Oct 2020 18:07:24
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System (b) (4)	31 Aug 2020 12:46:21
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	31 Aug 2020 12:46:21
User entered '18' reason for change: Data Entry Error	Megan Loughran (b) (4)	31 Aug 2020 12:46:21
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System (b) (4)	31 Aug 2020 12:46:02
User entered '28'	Megan Loughran (b) (4)	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'breaths/min'	System	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:27
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '137'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '63'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:10:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		06 Oct 2020 04:26:56
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'corrected' (Site from DM).	Son Do (b) (4)	05 Oct 2020 16:22:23
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:22:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:22:20
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:04:47
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '175.5' cm	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:46:02

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:10:36
Signature has been broken.	Son Do (b) (4)	05 Oct 2020 16:22:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	05 Oct 2020 16:22:20
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '77.3' kg	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Post-Dose (POSTDOSE)'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:36
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

US3642024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '16:47'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '27 Aug 2020 16:47'	System	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:41
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '97.9' F	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:43
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (Oral)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:45
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:47
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '55'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'bpm'	System	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:49
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '18'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'breaths/min'	System	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:50
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '132'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:07:52
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '69'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	31 Aug 2020 12:47:08

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:15:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Son Do (b) (4)	04 Feb 2021 16:55:37
User entered 'No (N)' reason for change: Data Entry	Son Do (b) (4)	04 Feb 2021 16:55:37
Error		
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:11:00
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4)	
	Megan Loughran (b) (4)	31 Aug 2020 12:47:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Son Do (b) (4)	04 Feb 2021 16:55:37
User entered empty; reason for change Data Entry Error	Son Do (b) (4)	04 Feb 2021 16:55:37
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:11:03
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '27 Aug 2020' reason for change: Data Entry Error	System	31 Aug 2020 12:47:31
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Megan Loughran (b) (4)	31 Aug 2020 12:47:31
User entered '31 Aug 2020'	(b) (4)	
	Megan Loughran (b) (4)	31 Aug 2020 12:47:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:11:44
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:11:46
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:11:50
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:57:03

US3642024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:11:53
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:13:35
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '15:45'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '27 Aug 2020 15:45'	System	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:13:46
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Megan Loughran (b) (4) (b) (4)	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:13:51
User entered 'ONCE'	System	27 Aug 2020 22:57:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 22:57:03

US3642024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:15:07
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:00

US3642024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:15:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:00

US3642024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:15:10
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '15:08'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:00

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '27 Aug 2020 15:08'	System	31 Aug 2020 12:48:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:09:46

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:15:19
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '27 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Megan Loughran (b) (4)	31 Aug 2020 12:48:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:08:45
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:22

US3642024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:08:49
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '15:13'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:22

US3642024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '27 Aug 2020 15:13'	System	31 Aug 2020 12:48:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Megan Loughran (b) (4)	31 Aug 2020 12:48:22

US3642024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:10:37
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:22

US3642024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		09 Oct 2020 18:10:39
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:22

US3642024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered empty.	System	31 Aug 2020 12:48:22

US3642024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		08 Oct 2020 17:15:27
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:30

US3642024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	31 Aug 2020 12:48:30

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T16:18:03', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '398acd12-16ae-4d65-8806-70ad88beb915' User entered 'Yes (Y)'	System	27 Aug 2020 23:18:34
	System	27 Aug 2020 23:18:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T16:18:16', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '398acd12-16ae-4d65-8806-70ad88beb915' User entered '97.9'	System	27 Aug 2020 23:18:34
	System	27 Aug 2020 23:18:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T16:18:23', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '398acd12-16ae-4d65-8806-70ad88beb915' User entered 'No (N)'	System	27 Aug 2020 23:18:34
	System	27 Aug 2020 23:18:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T16:18:29', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '398acd12-16ae-4d65-8806-70ad88beb915' User entered '27 Aug 2020 16:18'	System	27 Aug 2020 23:18:34
	System	27 Aug 2020 23:18:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 16:05'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 18:35'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:01', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a6d5abfb-e9a6-4644-92c6-bd1109c9b65f' User entered 'Yes (Y)'	System	28 Aug 2020 02:34:34
	System	28 Aug 2020 02:34:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:22', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a6d5abfb-e9a6-4644-92c6-bd1109c9b65f' User entered '98.0'	System	28 Aug 2020 02:34:34
	System	28 Aug 2020 02:34:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:26', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a6d5abfb-e9a6-4644-92c6-bd1109c9b65f' User entered 'No (N)'	System	28 Aug 2020 02:34:34
	System	28 Aug 2020 02:34:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:32', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a6d5abfb-e9a6-4644-92c6-bd1109c9b65f' User entered '27 Aug 2020 19:34'	System	28 Aug 2020 02:34:34
	System	28 Aug 2020 02:34:34

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 19:30'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 2'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T14:09:25', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6c7e6d94-74d8-4bda-98d4-649d6a849c7a' User entered 'Yes (Y)'	System	28 Aug 2020 21:09:54
	System	28 Aug 2020 21:09:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T14:09:41', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6c7e6d94-74d8-4bda-98d4-649d6a849c7a' User entered '97.1'	System	28 Aug 2020 21:09:54
	System	28 Aug 2020 21:09:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T14:09:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6c7e6d94-74d8-4bda-98d4-649d6a849c7a'	System	28 Aug 2020 21:09:54
User entered 'No (N)'	System	28 Aug 2020 21:09:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T14:09:52', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6c7e6d94-74d8-4bda-98d4-649d6a849c7a' User entered '28 Aug 2020 14:09'	System	28 Aug 2020 21:09:54
	System	28 Aug 2020 21:09:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 3'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 4'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:07', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '178f6b6a-f46a-4753-a4a3-0540b21c9103' User entered 'Yes (Y)'	System	30 Aug 2020 22:48:27
	System	30 Aug 2020 22:48:27

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:14', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '178f6b6a-f46a-4753-a4a3-0540b21c9103' User entered '98.0'	System	30 Aug 2020 22:48:27
	System	30 Aug 2020 22:48:27

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:18', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '178f6b6a-f46a-4753-a4a3-0540b21c9103'	System	30 Aug 2020 22:48:27
User entered 'No (N)'	System	30 Aug 2020 22:48:27

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:23', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '178f6b6a-f46a-4753-a4a3-0540b21c9103' User entered '30 Aug 2020 15:48'	System	30 Aug 2020 22:48:27
	System	30 Aug 2020 22:48:27

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 5'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:29', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '85798810-2d82-4539-b88c-96ff1f51b235'	System	01 Sep 2020 00:44:54
User entered 'Yes (Y)'	System	01 Sep 2020 00:44:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:36', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '85798810-2d82-4539-b88c-96ff1f51b235'	System	01 Sep 2020 00:44:54
User entered '97.8'	System	01 Sep 2020 00:44:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:41', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '85798810-2d82-4539-b88c-96ff1f51b235'	System	01 Sep 2020 00:44:54
User entered 'No (N)'	System	01 Sep 2020 00:44:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:53', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '85798810-2d82-4539-b88c-96ff1f51b235'	System	01 Sep 2020 00:44:54
User entered '31 Aug 2020 17:44'	System	01 Sep 2020 00:44:54

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 6'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:27', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'ccf076ee-6d66-4459-9e2c-bec4bfc49ad2'	System	02 Sep 2020 04:41:55
User entered 'Yes (Y)'	System	02 Sep 2020 04:41:55

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'ccf076ee-6d66-4459-9e2c-bec4bfc49ad2' User entered '97.9'	System	02 Sep 2020 04:41:55
	System	02 Sep 2020 04:41:55

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:49', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'ccf076ee-6d66-4459-9e2c-bec4bfc49ad2'	System	02 Sep 2020 04:41:55
User entered 'No (N)'	System	02 Sep 2020 04:41:55

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'ccf076ee-6d66-4459-9e2c-bec4bfc49ad2'	System	02 Sep 2020 04:41:55
User entered '01 Sep 2020 21:41'	System	02 Sep 2020 04:41:55

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 7'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T20:08:18', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'aa35f1ec-3c6d-40f5-b53e-508426235b5c' User entered 'Yes (Y)'	System	03 Sep 2020 03:08:47
	System	03 Sep 2020 03:08:47

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T20:08:31', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'aa35f1ec-3c6d-40f5-b53e-508426235b5c' User entered '98.2'	System	03 Sep 2020 03:08:47
	System	03 Sep 2020 03:08:47

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T20:08:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'aa35f1ec-3c6d-40f5-b53e-508426235b5c' User entered 'No (N)'	System	03 Sep 2020 03:08:47
	System	03 Sep 2020 03:08:47

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T20:08:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'aa35f1ec-3c6d-40f5-b53e-508426235b5c' User entered '02 Sep 2020 20:08'	System	03 Sep 2020 03:08:47
	System	03 Sep 2020 03:08:47

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T17:05:02', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9c75871d-c815-4308-82cf-99e83aedd48b' User entered 'None (1)'	System	28 Aug 2020 00:05:28
	System	28 Aug 2020 00:05:28

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T17:05:06', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9c75871d-c815-4308-82cf-99e83aedd48b' User entered 'No (N)'	System	28 Aug 2020 00:05:28
	System	28 Aug 2020 00:05:28

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T17:05:10', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9c75871d-c815-4308-82cf-99e83aedd48b' User entered 'No (N)'	System	28 Aug 2020 00:05:28
	System	28 Aug 2020 00:05:28

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T17:05:15', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9c75871d-c815-4308-82cf-99e83aedd48b' User entered 'None (1)'	System	28 Aug 2020 00:05:28
	System	28 Aug 2020 00:05:28

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T17:05:24', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9c75871d-c815-4308-82cf-99e83aedd48b' User entered '27 Aug 2020 17:05'	System	28 Aug 2020 00:05:28
	System	28 Aug 2020 00:05:28

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 16:05'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 18:35'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '78c91219-27fc-4a78-a3c4-9e991fefac71'	System	28 Aug 2020 02:35:03
User entered 'None (1)'	System	28 Aug 2020 02:35:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:48', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '78c91219-27fc-4a78-a3c4-9e991fefac71'	System	28 Aug 2020 02:35:03
User entered 'No (N)'	System	28 Aug 2020 02:35:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:52', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '78c91219-27fc-4a78-a3c4-9e991fefac71'	System	28 Aug 2020 02:35:03
User entered 'No (N)'	System	28 Aug 2020 02:35:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:56', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '78c91219-27fc-4a78-a3c4-9e991fefac71'	System	28 Aug 2020 02:35:03
User entered 'None (1)'	System	28 Aug 2020 02:35:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T19:34:59', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '78c91219-27fc-4a78-a3c4-9e991fefac71' User entered '27 Aug 2020 19:34'	System	28 Aug 2020 02:35:03
	System	28 Aug 2020 02:35:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 19:30'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 2'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:35', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b9971d82-d5aa-4179-8466-e668759198ba' User entered 'None (1)'	System	29 Aug 2020 17:47:50
	System	29 Aug 2020 17:47:50

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b9971d82-d5aa-4179-8466-e668759198ba' User entered 'No (N)'	System	29 Aug 2020 17:47:50
	System	29 Aug 2020 17:47:50

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:41', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b9971d82-d5aa-4179-8466-e668759198ba' User entered 'No (N)'	System	29 Aug 2020 17:47:50
	System	29 Aug 2020 17:47:50

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b9971d82-d5aa-4179-8466-e668759198ba' User entered 'None (1)'	System	29 Aug 2020 17:47:50
	System	29 Aug 2020 17:47:50

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:48', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b9971d82-d5aa-4179-8466-e668759198ba' User entered '29 Aug 2020 10:47'	System	29 Aug 2020 17:47:50
	System	29 Aug 2020 17:47:50

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 3'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

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)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 4'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:30', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '685917e2-bd71-451b-804b-a27c89ed9758'	System	30 Aug 2020 22:48:56
User entered 'None (1)'	System	30 Aug 2020 22:48:56

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:37', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '685917e2-bd71-451b-804b-a27c89ed9758'	System	30 Aug 2020 22:48:56
User entered 'No (N)'	System	30 Aug 2020 22:48:56

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:43', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '685917e2-bd71-451b-804b-a27c89ed9758' User entered 'No (N)'	System	30 Aug 2020 22:48:56
	System	30 Aug 2020 22:48:56

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:47', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '685917e2-bd71-451b-804b-a27c89ed9758'	System	30 Aug 2020 22:48:56
User entered 'None (1)'	System	30 Aug 2020 22:48:56

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:48:52', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '685917e2-bd71-451b-804b-a27c89ed9758'	System	30 Aug 2020 22:48:56
User entered '30 Aug 2020 15:48'	System	30 Aug 2020 22:48:56

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 5'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:06', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b91eea24-6cdc-4675-af7d-a881e44d2a2e'	System	01 Sep 2020 00:44:24
User entered 'None (1)'	System	01 Sep 2020 00:44:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:10', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b91eea24-6cdc-4675-af7d-a881e44d2a2e' User entered 'No (N)'	System	01 Sep 2020 00:44:24
	System	01 Sep 2020 00:44:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b91eea24-6cdc-4675-af7d-a881e44d2a2e' User entered 'No (N)'	System	01 Sep 2020 00:44:24
	System	01 Sep 2020 00:44:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:17', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b91eea24-6cdc-4675-af7d-a881e44d2a2e'	System	01 Sep 2020 00:44:24
User entered 'None (1)'	System	01 Sep 2020 00:44:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:44:22', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b91eea24-6cdc-4675-af7d-a881e44d2a2e' User entered '31 Aug 2020 17:44'	System	01 Sep 2020 00:44:24
	System	01 Sep 2020 00:44:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 6'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:09', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '66fda3b2-bfc4-4d00-a369-ec090a167fd' User entered 'None (1)'	System	02 Sep 2020 04:41:24
	System	02 Sep 2020 04:41:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:12', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '66fda3b2-bfc4-4d00-a369-ec090a167fd' User entered 'No (N)'	System	02 Sep 2020 04:41:24
	System	02 Sep 2020 04:41:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:15', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '66fda3b2-bfc4-4d00-a369-ec090a167fd' User entered 'No (N)'	System	02 Sep 2020 04:41:24
	System	02 Sep 2020 04:41:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:17', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '66fda3b2-bfc4-4d00-a369-ee090a167fd' User entered 'None (1)'	System	02 Sep 2020 04:41:24
	System	02 Sep 2020 04:41:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:21', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '66fda3b2-bfc4-4d00-a369-ee090a167fd' User entered '01 Sep 2020 21:41'	System	02 Sep 2020 04:41:24
	System	02 Sep 2020 04:41:24

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 7'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:29', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc2bd7d8-c1bd-4546-b42d-3b4b506cda58'	System	03 Sep 2020 00:17:48
User entered 'None (1)'	System	03 Sep 2020 00:17:48

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:33', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc2bd7d8-c1bd-4546-b42d-3b4b506cda58'	System	03 Sep 2020 00:17:48
User entered 'No (N)'	System	03 Sep 2020 00:17:48

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:35', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc2bd7d8-c1bd-4546-b42d-3b4b506cda58'	System	03 Sep 2020 00:17:48
User entered 'No (N)'	System	03 Sep 2020 00:17:48

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc2bd7d8-c1bd-4546-b42d-3b4b506cda58'	System	03 Sep 2020 00:17:48
User entered 'None (1)'	System	03 Sep 2020 00:17:48

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc2bd7d8-c1bd-4546-b42d-3b4b506cda58' User entered '02 Sep 2020 17:17'	System	03 Sep 2020 00:17:48
	System	03 Sep 2020 00:17:48

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:20:29', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a' User entered 'None (0)'	System	28 Aug 2020 01:21:07
	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:20:35', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a' User entered 'None (0)'	System	28 Aug 2020 01:21:07
	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:20:39', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a' User entered 'None (0)'	System	28 Aug 2020 01:21:07
	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:20:42', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a' User entered 'None (0)'	System	28 Aug 2020 01:21:07
	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:20:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a' User entered 'None (0)'	System	28 Aug 2020 01:21:07
	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:20:51', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a' User entered 'None (0)'	System	28 Aug 2020 01:21:07
	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:20:56', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a'	System	28 Aug 2020 01:21:07
User entered 'No (N)'	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-27T18:21:03', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'd076590d-96d5-40db-9d75-bbe15dd68c2a'	System	28 Aug 2020 01:21:07
User entered '27 Aug 2020 18:21'	System	28 Aug 2020 01:21:07

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 16:05'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 18:35'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:07', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3' User entered 'None (0)'	System	28 Aug 2020 17:00:46
	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:10', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3' User entered 'None (0)'	System	28 Aug 2020 17:00:46
	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3' User entered 'None (0)'	System	28 Aug 2020 17:00:46
	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:16', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3' User entered 'None (0)'	System	28 Aug 2020 17:00:46
	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:19', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3' User entered 'None (0)'	System	28 Aug 2020 17:00:46
	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:21', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3' User entered 'None (0)'	System	28 Aug 2020 17:00:46
	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:26', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3'	System	28 Aug 2020 17:00:46
User entered 'No (N)'	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-28T10:00:32', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8b47eea0-f86b-458f-9b28-0264a3e2f2d3'	System	28 Aug 2020 17:00:46
User entered '28 Aug 2020 10:00'	System	28 Aug 2020 17:00:46

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '27 Aug 2020 19:30'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 2'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:04', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered 'None (0)'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:07', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered 'None (0)'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:10', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered 'None (0)'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered 'None (0)'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:16', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered 'None (0)'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:19', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered 'None (0)'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:25', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered 'No (N)'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-29T10:47:28', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e118451-746a-4ac3-9a8c-271b0221c2bd' User entered '29 Aug 2020 10:47'	System	29 Aug 2020 17:47:33
	System	29 Aug 2020 17:47:33

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 3'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 4'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:01', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered 'None (0)'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:04', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered 'None (0)'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:06', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered 'None (0)'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:08', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered 'None (0)'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:11', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered 'None (0)'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:14', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered 'None (0)'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:17', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered 'No (N)'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-30T15:49:20', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1e3e3a56-9d7f-4db9-b208-c88317dbd46f' User entered '30 Aug 2020 15:49'	System	30 Aug 2020 22:49:21
	System	30 Aug 2020 22:49:21

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 5'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:34', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered 'None (0)'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:37', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered 'None (0)'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:40', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered 'None (0)'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:43', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered 'None (0)'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:48', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered 'None (0)'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:52', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered 'None (0)'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:55', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered 'No (N)'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-08-31T17:43:58', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3e64a7f0-c505-4fc8-abb1-591d336569ac' User entered '31 Aug 2020 17:43'	System	01 Sep 2020 00:44:01
	System	01 Sep 2020 00:44:01

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 6'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:40:43', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered 'None (0)'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:40:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered 'None (0)'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:40:48', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered 'None (0)'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:40:51', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered 'None (0)'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:40:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered 'None (0)'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:40:57', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered 'None (0)'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:01', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered 'No (N)'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-01T21:41:04', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'cb05b2a8-0488-4d3e-bf2f-d50fb3ec1ae0' User entered '01 Sep 2020 21:41'	System	02 Sep 2020 04:41:06
	System	02 Sep 2020 04:41:06

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 7'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:08', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered 'None (0)'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:10', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered 'None (0)'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:12', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered 'None (0)'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:14', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered 'None (0)'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:17', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered 'None (0)'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:19', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered 'None (0)'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:23', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered 'No (N)'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-09-02T17:17:25', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '795cae7a-280b-416e-b432-c25c3ce6b0c7' User entered '02 Sep 2020 17:17'	System	03 Sep 2020 00:17:29
	System	03 Sep 2020 00:17:29

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 22:57:03

US3642024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:45
User entered 'Yes (Y)'	Nancy Tang (b) (4)	07 Sep 2020 23:20:01

US3642024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:51
User entered '05 Sep 2020'	Nancy Tang (b) (4)	07 Sep 2020 23:20:01

US3642024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:54
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	07 Sep 2020 23:20:01

US3642024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:34:55
User entered empty.	Nancy Tang (b) (4)	07 Sep 2020 23:20:01

US3642024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:11:17
User entered 'Yes (Y)'	Nancy Tang (b) (4)	07 Sep 2020 23:20:06

US3642024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	07 Sep 2020 23:20:06

US3642024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:56:27
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:04:05

US3642024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:56:27
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		15 Sep 2020 16:47:47
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CALL MADE ONE DAY OUTSIDE OF TREATMENT WINDOW' (Site from System).	Colleen McLellan (b) (4)	14 Sep 2020 23:04:10
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 23:04:05
User entered '14 Sep 2020'	Colleen McLellan (b) (4)	14 Sep 2020 23:04:05

US3642024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:56:27
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:04:05

US3642024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:56:27
User entered empty.	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:04:05

US3642024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:56:31
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:04:14

US3642024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '1'	System	14 Sep 2020 23:04:14

US3642024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:23:02
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	22 Sep 2020 17:16:15

US3642024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:23:04
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		23 Sep 2020 06:10:04
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONTACT MADE OUTSIDE OF TREATMENT WINDOW' (Site from System).	Colleen McLellan (b) (4)	22 Sep 2020 17:16:44
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Sep 2020 17:16:15
User entered '22 Sep 2020'	Colleen McLellan (b) (4)	22 Sep 2020 17:16:15

US3642024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:23:07
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	22 Sep 2020 17:16:15

US3642024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:23:11
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Sep 2020 17:16:15

US3642024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:23:22
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	22 Sep 2020 17:16:49

US3642024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	22 Sep 2020 17:16:49

US3642024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:25:54
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:51:13

US3642024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:25:54
User entered '1 Oct 2020'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:51:13

US3642024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:25:54
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 21:51:13

US3642024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'VISIT2'	System	01 Oct 2020 21:51:13

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:38
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:40
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:41
User entered '14:20'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '01 Oct 2020 14:20'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:43
User entered '98.6' F	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:44
User entered 'Oral (Oral)'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:47
User entered '73'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'bpm'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:57:31
Query 'Per source RR is documented as 16. Please review and reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:57:28
User opened query 'Per source RR is documented as 16. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:30:33
User entered '18'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'breaths/min'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:50
User entered '132'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:30:51
User entered '66'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '01 Oct 2020'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '17:08'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '01 Oct 2020 17:08'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '98.7' F	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '70'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'bpm'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '17'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'breaths/min'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '136'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:03
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '62'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	05 Oct 2020 16:23:09

US3642024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:31:34
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:23:18

US3642024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:31:34
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:23:18

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:43:27
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:43:27
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:43:27
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:43:27
User entered '1 Oct 2020'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:43:27
User entered '16:34'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '1 Oct 2020 16:34'	System	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:43:27
User entered 'Left Arm (LEFT ARM)'	Megan Loughran (b) (4) (b) (4)	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		22 Oct 2020 16:43:27
User entered 'ONCE'	System	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 23:38:30

US3642024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:19
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:23:31

US3642024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:19
User entered '01 Oct 2020'	Son Do (b) (4)	05 Oct 2020 16:23:31

US3642024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:19
User entered '15:05'	Son Do (b) (4)	05 Oct 2020 16:23:31

US3642024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '01 Oct 2020 15:05'	System	05 Oct 2020 16:23:31

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:09:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:13
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '01 Oct 2020'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:34
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:36
User entered '15:00'	Son Do (b) (4)	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '01 Oct 2020 15:00'	System	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:13
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'No (N)'	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:15:13
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered empty.	(b) (4) Son Do (b) (4)	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered empty.	System	05 Oct 2020 16:23:45

US3642024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		14 Apr 2021 20:01:57
DataPoint Un-verified.		14 Apr 2021 20:01:54
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:44:42
User entered 'Yes (Y)'	Son Do (b) (4)	05 Oct 2020 16:23:52

US3642024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	05 Oct 2020 16:23:52

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:06:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '41340321-b444-40bc-afee-9c0606e051e9' User entered 'Yes (Y)'	System	02 Oct 2020 00:06:56
	System	02 Oct 2020 00:06:56

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:06:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '41340321-b444-40bc-afee-9c0606e051e9' User entered '98.7'	System	02 Oct 2020 00:06:56
	System	02 Oct 2020 00:06:56

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:06:49', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '41340321-b444-40bc-afee-9c0606e051e9'	System	02 Oct 2020 00:06:56
User entered 'No (N)'	System	02 Oct 2020 00:06:56

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:06:53', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '41340321-b444-40bc-afee-9c0606e051e9' User entered '01 Oct 2020 17:06'	System	02 Oct 2020 00:06:56
	System	02 Oct 2020 00:06:56

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 16:54'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 19:24'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:22', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'bebbe281-ccf7-4513-bd9d-58334615326b' User entered 'Yes (Y)'	System	02 Oct 2020 05:56:48
	System	02 Oct 2020 05:56:48

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:37', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'bebbe281-ccf7-4513-bd9d-58334615326b' User entered '97.7'	System	02 Oct 2020 05:56:48
	System	02 Oct 2020 05:56:48

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:42', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'bebbe281-ccf7-4513-bd9d-58334615326b' User entered 'No (N)'	System	02 Oct 2020 05:56:48
	System	02 Oct 2020 05:56:48

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'bebbe281-ccf7-4513-bd9d-58334615326b' User entered '01 Oct 2020 22:56'	System	02 Oct 2020 05:56:48
	System	02 Oct 2020 05:56:48

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 20:19'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 2'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '375be42b-c4bb-452f-bca5-454fb4596561' User entered 'Yes (Y)'	System	02 Oct 2020 19:34:08
	System	02 Oct 2020 19:34:08

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '375be42b-c4bb-452f-bca5-454fb4596561' User entered '98.1'	System	02 Oct 2020 19:34:08
	System	02 Oct 2020 19:34:08

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:59', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '375be42b-c4bb-452f-bca5-454fb4596561' User entered 'No (N)'	System	02 Oct 2020 19:34:08
	System	02 Oct 2020 19:34:08

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:34:03', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '375be42b-c4bb-452f-bca5-454fb4596561' User entered '02 Oct 2020 12:34'	System	02 Oct 2020 19:34:08
	System	02 Oct 2020 19:34:08

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 3'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:37:07', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '312170a4-3017-4561-919d-4c61a28caff0' User entered 'Yes (Y)'	System	03 Oct 2020 20:37:30
	System	03 Oct 2020 20:37:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:37:17', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '312170a4-3017-4561-919d-4c61a28caff0' User entered '98.2'	System	03 Oct 2020 20:37:30
	System	03 Oct 2020 20:37:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:37:22', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '312170a4-3017-4561-919d-4c61a28caff0'	System	03 Oct 2020 20:37:30
User entered 'No (N)'	System	03 Oct 2020 20:37:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:37:26', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '312170a4-3017-4561-919d-4c61a28caff0' User entered '03 Oct 2020 13:37'	System	03 Oct 2020 20:37:30
	System	03 Oct 2020 20:37:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 4'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '957c64b5-b304-4148-85ab-2279262c101e' User entered 'Yes (Y)'	System	04 Oct 2020 19:14:04
	System	04 Oct 2020 19:14:04

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '957c64b5-b304-4148-85ab-2279262c101e' User entered '98.2'	System	04 Oct 2020 19:14:04
	System	04 Oct 2020 19:14:04

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:57', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '957c64b5-b304-4148-85ab-2279262c101e' User entered 'No (N)'	System	04 Oct 2020 19:14:04
	System	04 Oct 2020 19:14:04

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:14:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '957c64b5-b304-4148-85ab-2279262c101e' User entered '04 Oct 2020 12:14'	System	04 Oct 2020 19:14:04
	System	04 Oct 2020 19:14:04

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 5'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6281d8f4-64d2-45ad-9c3c-5fa3c52880f1' User entered 'Yes (Y)'	System	06 Oct 2020 05:07:03
	System	06 Oct 2020 05:07:03

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6281d8f4-64d2-45ad-9c3c-5fa3c52880f1' User entered '98.1'	System	06 Oct 2020 05:07:03
	System	06 Oct 2020 05:07:03

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:58', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6281d8f4-64d2-45ad-9c3c-5fa3c52880f1' User entered 'No (N)'	System	06 Oct 2020 05:07:03
	System	06 Oct 2020 05:07:03

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6281d8f4-64d2-45ad-9c3c-5fa3c52880f1' User entered '05 Oct 2020 22:07'	System	06 Oct 2020 05:07:03
	System	06 Oct 2020 05:07:03

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 6'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 7'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:04:07', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4c8b3538-fd44-4ad4-b7eb-077913086498'	System	02 Oct 2020 00:06:08
User entered 'None (1)'	System	02 Oct 2020 00:06:08

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:05:50', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4c8b3538-fd44-4ad4-b7eb-077913086498' User entered 'No (N)'	System	02 Oct 2020 00:06:08
	System	02 Oct 2020 00:06:08

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:05:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4c8b3538-fd44-4ad4-b7eb-077913086498' User entered 'No (N)'	System	02 Oct 2020 00:06:08
	System	02 Oct 2020 00:06:08

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:06:01', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4c8b3538-fd44-4ad4-b7eb-077913086498'	System	02 Oct 2020 00:06:08
User entered 'None (1)'	System	02 Oct 2020 00:06:08

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:06:04', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4c8b3538-fd44-4ad4-b7eb-077913086498' User entered '01 Oct 2020 17:06'	System	02 Oct 2020 00:06:08
	System	02 Oct 2020 00:06:08

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 16:54'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 19:24'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:58', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e7dcf587-0d27-4658-85d7-99dbc262f718'	System	02 Oct 2020 05:56:16
User entered 'None (1)'	System	02 Oct 2020 05:56:16

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:02', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e7dcf587-0d27-4658-85d7-99dbc262f718' User entered 'No (N)'	System	02 Oct 2020 05:56:16
	System	02 Oct 2020 05:56:16

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:06', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e7dcf587-0d27-4658-85d7-99dbc262f718' User entered 'No (N)'	System	02 Oct 2020 05:56:16
	System	02 Oct 2020 05:56:16

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:10', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e7dcf587-0d27-4658-85d7-99dbc262f718' User entered 'None (1)'	System	02 Oct 2020 05:56:16
	System	02 Oct 2020 05:56:16

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:56:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e7dcf587-0d27-4658-85d7-99dbc262f718' User entered '01 Oct 2020 22:56'	System	02 Oct 2020 05:56:16
	System	02 Oct 2020 05:56:16

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 20:19'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 2'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:22', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f6a7de2c-ecc5-4378-ab8c-40cc3968bbd8'	System	02 Oct 2020 19:33:41
User entered 'None (1)'	System	02 Oct 2020 19:33:41

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:25', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f6a7de2c-ecc5-4378-ab8c-40cc3968bbd8' User entered 'No (N)'	System	02 Oct 2020 19:33:41
	System	02 Oct 2020 19:33:41

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:28', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f6a7de2c-ecc5-4378-ab8c-40cc3968bbd8'	System	02 Oct 2020 19:33:41
User entered 'No (N)'	System	02 Oct 2020 19:33:41

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:32', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f6a7de2c-ecc5-4378-ab8c-40cc3968bbd8'	System	02 Oct 2020 19:33:41
User entered 'None (1)'	System	02 Oct 2020 19:33:41

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:34', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f6a7de2c-ecc5-4378-ab8c-40cc3968bbd8' User entered '02 Oct 2020 12:33'	System	02 Oct 2020 19:33:41
	System	02 Oct 2020 19:33:41

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 3'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7e26591f-7214-4fce-88d6-eaf85f1c5568'	System	03 Oct 2020 20:37:00
User entered 'None (1)'	System	03 Oct 2020 20:37:00

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:49', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7e26591f-7214-4fce-88d6-eaf85f1c5568' User entered 'No (N)'	System	03 Oct 2020 20:37:00
	System	03 Oct 2020 20:37:00

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:51', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7e26591f-7214-4fce-88d6-eaf85f1c5568' User entered 'No (N)'	System	03 Oct 2020 20:37:00
	System	03 Oct 2020 20:37:00

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:55', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7e26591f-7214-4fce-88d6-eaf85f1c5568'	System	03 Oct 2020 20:37:00
User entered 'None (1)'	System	03 Oct 2020 20:37:00

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:59', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7e26591f-7214-4fce-88d6-eaf85f1c5568' User entered '03 Oct 2020 13:36'	System	03 Oct 2020 20:37:00
	System	03 Oct 2020 20:37:00

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 4'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:11', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '54c2ecf6-9738-403f-bd53-1a3edd96c341'	System	04 Oct 2020 19:13:25
User entered 'None (1)'	System	04 Oct 2020 19:13:25

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:14', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '54c2ecf6-9738-403f-bd53-1a3edd96c341' User entered 'No (N)'	System	04 Oct 2020 19:13:25
	System	04 Oct 2020 19:13:25

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:16', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '54c2ecf6-9738-403f-bd53-1a3edd96c341' User entered 'No (N)'	System	04 Oct 2020 19:13:25
	System	04 Oct 2020 19:13:25

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:19', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '54c2ecf6-9738-403f-bd53-1a3edd96c341' User entered 'None (1)'	System	04 Oct 2020 19:13:25
	System	04 Oct 2020 19:13:25

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:22', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '54c2ecf6-9738-403f-bd53-1a3edd96c341' User entered '04 Oct 2020 12:13'	System	04 Oct 2020 19:13:25
	System	04 Oct 2020 19:13:25

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 5'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:15', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0a851e78-c8cb-48f5-8940-603dadabb7f2' User entered 'None (1)'	System	06 Oct 2020 05:06:40
	System	06 Oct 2020 05:06:40

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:26', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0a851e78-c8cb-48f5-8940-603dadabb7f2' User entered 'No (N)'	System	06 Oct 2020 05:06:40
	System	06 Oct 2020 05:06:40

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:29', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0a851e78-c8cb-48f5-8940-603dadabb7f2' User entered 'No (N)'	System	06 Oct 2020 05:06:40
	System	06 Oct 2020 05:06:40

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:34', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0a851e78-c8cb-48f5-8940-603dadabb7f2' User entered 'None (1)'	System	06 Oct 2020 05:06:40
	System	06 Oct 2020 05:06:40

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:06:37', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0a851e78-c8cb-48f5-8940-603dadabb7f2' User entered '05 Oct 2020 22:06'	System	06 Oct 2020 05:06:40
	System	06 Oct 2020 05:06:40

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 6'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

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)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 7'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

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)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:01:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3' User entered 'None (0)'	System	02 Oct 2020 00:03:02
	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:01:55', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3' User entered 'None (0)'	System	02 Oct 2020 00:03:02
	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:02:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3'	System	02 Oct 2020 00:03:02
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:02:24', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3'	System	02 Oct 2020 00:03:02
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:02:28', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3' User entered 'None (0)'	System	02 Oct 2020 00:03:02
	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:02:31', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3' User entered 'None (0)'	System	02 Oct 2020 00:03:02
	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:02:55', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3' User entered 'No (N)'	System	02 Oct 2020 00:03:02
	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T17:02:59', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a00d5ff6-93c6-46db-80b6-21c83d47e4e3' User entered '01 Oct 2020 17:02'	System	02 Oct 2020 00:03:02
	System	02 Oct 2020 00:03:02

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 16:54'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 19:24'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:27', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered 'None (0)'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:32', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered 'None (0)'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:36', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered 'None (0)'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:40', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered 'None (0)'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered 'None (0)'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered 'None (0)'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:50', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered 'No (N)'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-01T22:55:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0156eb21-9b54-419f-b9ea-880c4ca789e3' User entered '01 Oct 2020 22:55'	System	02 Oct 2020 05:55:55
	System	02 Oct 2020 05:55:55

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '01 Oct 2020 20:19'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 2'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:32:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered 'None (0)'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:32:49', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered 'None (0)'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:32:52', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered 'None (0)'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:32:55', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered 'None (0)'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:32:59', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered 'None (0)'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:09', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered 'None (0)'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:14', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered 'No (N)'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-02T12:33:17', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a1f05d9a-0fe6-454b-bc79-859f9119c80b' User entered '02 Oct 2020 12:33'	System	02 Oct 2020 19:33:22
	System	02 Oct 2020 19:33:22

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 3'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered 'None (0)'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:16', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered 'None (0)'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:19', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered 'None (0)'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:21', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered 'None (0)'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:25', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered 'None (0)'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:28', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered 'None (0)'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:32', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered 'No (N)'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-03T13:36:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7371bac7-3923-4b62-9122-641ed204658b' User entered '03 Oct 2020 13:36'	System	03 Oct 2020 20:36:40
	System	03 Oct 2020 20:36:40

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 4'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:12:50', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered 'None (0)'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:12:52', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered 'None (0)'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:12:54', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered 'None (0)'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:12:56', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered 'None (0)'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:12:58', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered 'None (0)'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:01', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered 'None (0)'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:05', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered 'No (N)'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-04T12:13:07', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'be4fdc30-e68d-40b4-b7bc-6b6d5439868c' User entered '04 Oct 2020 12:13'	System	04 Oct 2020 19:13:09
	System	04 Oct 2020 19:13:09

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 5'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:31', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered 'None (0)'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:34', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered 'None (0)'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:36', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered 'None (0)'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered 'None (0)'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:40', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered 'None (0)'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:43', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered 'None (0)'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:47', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered 'No (N)'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-05T22:05:49', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'c9dee70f-f2cd-4425-a7c5-14bc3c252df9' User entered '05 Oct 2020 22:05'	System	06 Oct 2020 05:05:51
	System	06 Oct 2020 05:05:51

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 6'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	01 Oct 2020 23:38:30
User entered 'Day 7'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:04', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered 'None (0)'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:08', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered 'None (0)'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:13', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered 'None (0)'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:16', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered 'None (0)'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:21', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered 'None (0)'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:24', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered 'None (0)'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:31', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered 'No (N)'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-08T11:59:35', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '1cf8ecbf-d462-4f81-98db-e139c3375a3e' User entered '08 Oct 2020 11:59'	System	08 Oct 2020 18:59:37
	System	08 Oct 2020 18:59:37

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 23:38:30

US3642024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 23:38:30

US3642024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:51:57
User entered 'Yes (Y)'	Nancy Tang (b) (4)	12 Oct 2020 18:31:46

US3642024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:10:32
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONTACT MADE OUTSIDE OF TREATMENT WINDOW ' (Site from System).	Colleen McLellan (b) (4) (b) (4)	05 Nov 2020 18:52:55
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:51:53
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Oct 2020 18:31:46
User entered '12 Oct 2020'	Nancy Tang (b) (4)	12 Oct 2020 18:31:46

US3642024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:52:00
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	12 Oct 2020 18:31:46

US3642024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:52:02
User entered '3 ATTEMPTS MADE UNSUCCESSFUL AND CONTACT MADE OUT OF WINDOW 10/12/20 ATTEMPT 1 10/9 11:28AM ATTEMPT 2 10/10 6PM ATTEMPT 3 10/12 10:50AM CONTACT MADE 10/12 11AM' reason for change: Data Entry Error	Nancy Tang (b) (4)	12 Oct 2020 18:33:58
User entered empty.	Nancy Tang (b) (4)	12 Oct 2020 18:31:46

US3642024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:53:28
User entered 'Yes (Y)'	Nancy Tang (b) (4)	12 Oct 2020 18:31:55

US3642024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	12 Oct 2020 18:31:55

US3642024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:40
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	19 Oct 2020 18:45:36

US3642024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:14:40
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:17:43
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Call made late' (Site from System).	Benjamin Hull (b) (4) (b) (4)	05 Nov 2020 18:45:09
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Oct 2020 18:45:36
User entered '19 Oct 2020'	Nancy Tang (b) (4)	19 Oct 2020 18:45:36

US3642024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:40
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	19 Oct 2020 18:45:36

US3642024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:40
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'CONTACT MADE OUT OF WINDOW ATTEMPT 1 19OCT2020 11:08AM' reason for change: New Information	(b) (4) Nancy Tang (b) (4)	19 Oct 2020 18:46:20
User entered empty.	Nancy Tang (b) (4)	19 Oct 2020 18:45:36

US3642024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	19 Oct 2020 18:45:44

US3642024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	19 Oct 2020 18:45:44

US3642024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:10
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	25 Oct 2020 16:31:46

US3642024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:10
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '24 Oct 2020'	(b) (4) Nancy Tang (b) (4)	25 Oct 2020 16:31:46

US3642024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:10
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	25 Oct 2020 16:31:46

US3642024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:10
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Nancy Tang (b) (4)	25 Oct 2020 16:31:46

US3642024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	25 Oct 2020 16:31:50

US3642024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	25 Oct 2020 16:31:50

US3642024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:08

US3642024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '28 Oct 2020'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:08

US3642024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:14:22
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:08

US3642024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'VISIT3'	System	30 Oct 2020 15:17:08

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '28 Oct 2020'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '13:13'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '28 Oct 2020 13:13'	System	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '98.3' F	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered empty.	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '75'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'bpm'	System	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '16'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'breaths/min'	System	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '148'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '70'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'mmHg'	System	30 Oct 2020 15:17:31

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16

US3642024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16

US3642024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:29
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:40

US3642024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:14:29
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '28 Oct 2020'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:40

US3642024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:04:33
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:52

US3642024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:04:33
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '28 Oct 2020'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:52

US3642024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:04:33
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered '13:35'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:52

US3642024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '28 Oct 2020 13:35'	System	30 Oct 2020 15:17:52

US3642024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:04:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:59
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	30 Oct 2020 15:17:56

US3642024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered '1'	System	30 Oct 2020 15:17:56

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 64'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-29T12:50:34', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'fd4630cb-ae47-4178-a796-75962f7930cb' User entered 'No (N)'	System	29 Oct 2020 19:50:46
	System	29 Oct 2020 19:50:46

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-29T12:50:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'fd4630cb-ae47-4178-a796-75962f7930cb'	System	29 Oct 2020 19:50:46
User entered 'No (N)'	System	29 Oct 2020 19:50:46

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-10-29T12:50:43', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'fd4630cb-ae47-4178-a796-75962f7930cb' User entered '29 Oct 2020 12:50:43'	System	29 Oct 2020 19:50:46
	System	29 Oct 2020 19:50:46

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 71'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-05T10:08:57', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3523d57a-4bbb-4da9-bc0b-7ccad38ceb81' User entered 'No (N)'	System	05 Nov 2020 18:09:08
	System	05 Nov 2020 18:09:08

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-05T10:09:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3523d57a-4bbb-4da9-bc0b-7ccad38ceb81'	System	05 Nov 2020 18:09:08
User entered 'No (N)'	System	05 Nov 2020 18:09:08

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-05T10:09:03', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3523d57a-4bbb-4da9-bc0b-7ccad38ceb81' User entered '05 Nov 2020 10:09:03'	System	05 Nov 2020 18:09:08
	System	05 Nov 2020 18:09:08

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered 'Day 78'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-10T00:01:32', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4bd67baf-2adc-4285-be46-4e0999b74f16'	System	10 Nov 2020 08:01:55
User entered 'No (N)'	System	10 Nov 2020 08:01:55

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-10T00:01:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4bd67baf-2adc-4285-be46-4e0999b74f16'	System	10 Nov 2020 08:01:55
User entered 'No (N)'	System	10 Nov 2020 08:01:55

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-10T00:01:53', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '4bd67baf-2adc-4285-be46-4e0999b74f16' User entered '10 Nov 2020 00:01:53'	System	10 Nov 2020 08:01:55
	System	10 Nov 2020 08:01:55

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 22:57:03

US3642024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:42:19
Data entry locked.	System	27 Aug 2020 22:57:03
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 22:57:03

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-24T21:57:36', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f07e3df2-67f6-4905-b8b4-347717a16a73'	System	25 Nov 2020 05:57:55
User entered 'No (N)'	System	25 Nov 2020 05:57:55

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-24T21:57:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f07e3df2-67f6-4905-b8b4-347717a16a73'	System	25 Nov 2020 05:57:55
User entered 'No (N)'	System	25 Nov 2020 05:57:55

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-11-24T21:57:50', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'f07e3df2-67f6-4905-b8b4-347717a16a73' User entered '24 Nov 2020 21:57:50'	System	25 Nov 2020 05:57:55
	System	25 Nov 2020 05:57:55

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-02T11:59:34', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7215d7fb-17e8-4df0-a9f9-4739a6c26663' User entered 'No (N)'	System	02 Dec 2020 19:59:47
	System	02 Dec 2020 19:59:47

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-02T11:59:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7215d7fb-17e8-4df0-a9f9-4739a6c26663'	System	02 Dec 2020 19:59:47
User entered 'No (N)'	System	02 Dec 2020 19:59:47

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-02T11:59:42', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7215d7fb-17e8-4df0-a9f9-4739a6c26663' User entered '02 Dec 2020 11:59:42'	System	02 Dec 2020 19:59:47
	System	02 Dec 2020 19:59:47

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-05T10:43:40', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '523e8851-92b0-4e12-99bc-648f70ff7abb' User entered 'No (N)'	System	05 Dec 2020 18:43:50
	System	05 Dec 2020 18:43:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-05T10:43:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '523e8851-92b0-4e12-99bc-648f70ff7abb'	System	05 Dec 2020 18:43:50
User entered 'No (N)'	System	05 Dec 2020 18:43:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-05T10:43:47', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '523e8851-92b0-4e12-99bc-648f70ff7abb' User entered '05 Dec 2020 10:43:47'	System	05 Dec 2020 18:43:50
	System	05 Dec 2020 18:43:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-12T10:08:27', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '385d36e2-fb72-4dd9-9b22-5b603633023b' User entered 'No (N)'	System	12 Dec 2020 18:08:41
	System	12 Dec 2020 18:08:41

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-12T10:08:34', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '385d36e2-fb72-4dd9-9b22-5b603633023b' User entered 'No (N)'	System	12 Dec 2020 18:08:41

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-12T10:08:38', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '385d36e2-fb72-4dd9-9b22-5b603633023b' User entered '12 Dec 2020 10:08:38'	System	12 Dec 2020 18:08:41
	System	12 Dec 2020 18:08:41

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-19T10:48:28', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '049132c5-03c2-443d-bfa1-ac1946ac4457'	System	19 Dec 2020 18:48:53
User entered 'No (N)'	System	19 Dec 2020 18:48:53

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-19T10:48:40', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '049132c5-03c2-443d-bfa1-ac1946ac4457' User entered 'No (N)'	System	19 Dec 2020 18:48:53
	System	19 Dec 2020 18:48:53

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-19T10:48:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '049132c5-03c2-443d-bfa1-ac1946ac4457' User entered '19 Dec 2020 10:48:45'	System	19 Dec 2020 18:48:53
	System	19 Dec 2020 18:48:53

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-26T11:16:48', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '680d36ec-940f-44a2-9c8c-06cde3d131c9' User entered 'No (N)'	System	26 Dec 2020 19:17:02
	System	26 Dec 2020 19:17:02

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-26T11:16:53', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '680d36ec-940f-44a2-9c8c-06cde3d131c9' User entered 'No (N)'	System	26 Dec 2020 19:17:02
	System	26 Dec 2020 19:17:02

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2020-12-26T11:17:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '680d36ec-940f-44a2-9c8c-06cde3d131c9' User entered '26 Dec 2020 11:17:00'	System	26 Dec 2020 19:17:02
	System	26 Dec 2020 19:17:02

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-02T09:58:45', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9a631b43-b9f4-4cbb-b357-cb540736c892' User entered 'No (N)'	System	02 Jan 2021 17:58:57
	System	02 Jan 2021 17:58:57

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-02T09:58:50', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9a631b43-b9f4-4cbb-b357-cb540736c892' User entered 'No (N)'	System	02 Jan 2021 17:58:57
	System	02 Jan 2021 17:58:57

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-02T09:58:53', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9a631b43-b9f4-4cbb-b357-cb540736c892' User entered '02 Jan 2021 09:58:53'	System	02 Jan 2021 17:58:57
	System	02 Jan 2021 17:58:57

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-09T00:01:42', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e0a557a3-8658-4a86-bf87-58c3aa74a055'	System	09 Jan 2021 08:01:57
User entered 'No (N)'	System	09 Jan 2021 08:01:57

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-09T00:01:49', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e0a557a3-8658-4a86-bf87-58c3aa74a055'	System	09 Jan 2021 08:01:57
User entered 'No (N)'	System	09 Jan 2021 08:01:57

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-09T00:01:53', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'e0a557a3-8658-4a86-bf87-58c3aa74a055' User entered '09 Jan 2021 00:01:53'	System	09 Jan 2021 08:01:57
	System	09 Jan 2021 08:01:57

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-17T21:45:31', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '77165de5-a0a6-4bf1-a001-380ddf1f9282' User entered 'No (N)'	System	18 Jan 2021 05:47:18
	System	18 Jan 2021 05:47:18

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-17T21:47:11', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '77165de5-a0a6-4bf1-a001-380ddf1f9282'	System	18 Jan 2021 05:47:18
User entered 'No (N)'	System	18 Jan 2021 05:47:18

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-17T21:47:16', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '77165de5-a0a6-4bf1-a001-380ddf1f9282' User entered '17 Jan 2021 21:47:16'	System	18 Jan 2021 05:47:18
	System	18 Jan 2021 05:47:18

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-23T10:23:21', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a0ddd6fa-f56f-4078-b436-41f26fd53487'	System	29 Jan 2021 23:40:44
User entered 'No (N)'	System	29 Jan 2021 23:40:44

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-23T10:23:32', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a0ddd6fa-f56f-4078-b436-41f26fd53487'	System	29 Jan 2021 23:40:44
User entered 'No (N)'	System	29 Jan 2021 23:40:44

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-23T10:23:36', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'a0ddd6fa-f56f-4078-b436-41f26fd53487'	System	29 Jan 2021 23:40:44
User entered '23 Jan 2021 10:23:36'	System	29 Jan 2021 23:40:44

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-31T13:36:39', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6e146c0a-a91a-4300-9d99-cbdaa3c83bb1' User entered 'No (N)'	System	31 Jan 2021 21:36:50
	System	31 Jan 2021 21:36:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-31T13:36:44', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6e146c0a-a91a-4300-9d99-cbdaa3c83bb1' User entered 'No (N)'	System	31 Jan 2021 21:36:50
	System	31 Jan 2021 21:36:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-01-31T13:36:47', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '6e146c0a-a91a-4300-9d99-cbdaa3c83bb1' User entered '31 Jan 2021 13:36:47'	System	31 Jan 2021 21:36:50
	System	31 Jan 2021 21:36:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-07T17:03:24', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc890499-50b3-40eb-895a-262bc5204f1c'	System	11 Feb 2021 06:59:38
User entered 'No (N)'	System	11 Feb 2021 06:59:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-07T17:03:28', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc890499-50b3-40eb-895a-262bc5204f1c'	System	11 Feb 2021 06:59:38
User entered 'No (N)'	System	11 Feb 2021 06:59:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-07T17:03:31', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'dc890499-50b3-40eb-895a-262bc5204f1c' User entered '07 Feb 2021 17:03:31'	System	11 Feb 2021 06:59:38
	System	11 Feb 2021 06:59:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-13T20:57:40', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '30be52d7-60fa-4fd2-80e2-523c1d7047bc'	System	15 Feb 2021 07:13:01
User entered 'No (N)'	System	15 Feb 2021 07:13:01

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-13T20:57:46', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '30be52d7-60fa-4fd2-80e2-523c1d7047bc'	System	15 Feb 2021 07:13:01
User entered 'No (N)'	System	15 Feb 2021 07:13:01

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-13T20:57:49', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '30be52d7-60fa-4fd2-80e2-523c1d7047bc'	System	15 Feb 2021 07:13:01
User entered '13 Feb 2021 20:57:49'	System	15 Feb 2021 07:13:01

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-20T19:02:08', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0b59d330-3e37-49df-8c18-35e901e6d356'	System	21 Feb 2021 03:05:28
User entered 'No (N)'	System	21 Feb 2021 03:05:28

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-20T19:02:14', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0b59d330-3e37-49df-8c18-35e901e6d356'	System	21 Feb 2021 03:05:28
User entered 'No (N)'	System	21 Feb 2021 03:05:28

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-20T19:02:17', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0b59d330-3e37-49df-8c18-35e901e6d356'	System	21 Feb 2021 03:05:28
User entered '20 Feb 2021 19:02:17'	System	21 Feb 2021 03:05:28

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-27T00:02:24', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '049d0e8b-8a96-4da3-90aa-288488b85f47'	System	27 Feb 2021 08:02:35
User entered 'No (N)'	System	27 Feb 2021 08:02:35

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-27T00:02:27', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '049d0e8b-8a96-4da3-90aa-288488b85f47' User entered 'No (N)'	System	27 Feb 2021 08:02:35
	System	27 Feb 2021 08:02:35

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-27T00:02:30', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '049d0e8b-8a96-4da3-90aa-288488b85f47' User entered '27 Feb 2021 00:02:30'	System	27 Feb 2021 08:02:35
	System	27 Feb 2021 08:02:35

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-08T14:51:13-08:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'ea7a7f7b-1662-4677-a042-b5d11688700a' User entered 'No (N)'	System	08 Mar 2021 22:51:23
	System	08 Mar 2021 22:51:23

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-08T14:51:18-08:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'ea7a7f7b-1662-4677-a042-b5d11688700a' User entered 'No (N)'	System	08 Mar 2021 22:51:23
	System	08 Mar 2021 22:51:23

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-08T14:51:21-08:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'ea7a7f7b-1662-4677-a042-b5d11688700a' User entered '08 Mar 2021 14:51:21'	System	08 Mar 2021 22:51:23
	System	08 Mar 2021 22:51:23

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-15T21:50:18-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'abb20400-381d-46cc-bccb-b4ca38e02ac6'	System	16 Mar 2021 04:50:50
User entered 'No (N)'	System	16 Mar 2021 04:50:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-15T21:50:43-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'abb20400-381d-46cc-bccb-b4ca38e02ac6'	System	16 Mar 2021 04:50:50
User entered 'No (N)'	System	16 Mar 2021 04:50:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-15T21:50:47-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'abb20400-381d-46cc-bccb-b4ca38e02ac6' User entered '15 Mar 2021 21:50:47'	System	16 Mar 2021 04:50:50
	System	16 Mar 2021 04:50:50

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-22T16:37:41-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '18d19aba-8afb-4bb7-bd00-fbfeb66e95af'	System	22 Mar 2021 23:38:08
User entered 'No (N)'	System	22 Mar 2021 23:38:08

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-22T16:38:00-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '18d19aba-8afb-4bb7-bd00-fbfeb66e95af'	System	22 Mar 2021 23:38:08
User entered 'No (N)'	System	22 Mar 2021 23:38:08

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-22T16:38:04-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '18d19aba-8afb-4bb7-bd00-fbfeb66e95af' User entered '22 Mar 2021 16:38:04'	System	22 Mar 2021 23:38:08
	System	22 Mar 2021 23:38:08

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-27T15:59:18-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b812116d-00d3-496b-a4f9-7a6b20ddac96'	System	27 Mar 2021 22:59:30
User entered 'No (N)'	System	27 Mar 2021 22:59:30

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-27T15:59:21-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b812116d-00d3-496b-a4f9-7a6b20ddac96'	System	27 Mar 2021 22:59:30
User entered 'No (N)'	System	27 Mar 2021 22:59:30

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-03-27T15:59:25-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'b812116d-00d3-496b-a4f9-7a6b20ddac96'	System	27 Mar 2021 22:59:30
User entered '27 Mar 2021 15:59:25'	System	27 Mar 2021 22:59:30

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-06T19:12:29-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8ea676f7-2069-46b2-9382-72ecf137b5e5'	System	07 Apr 2021 02:12:51
User entered 'No (N)'	System	07 Apr 2021 02:12:51

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-06T19:12:35-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8ea676f7-2069-46b2-9382-72ecf137b5e5'	System	07 Apr 2021 02:12:51
User entered 'No (N)'	System	07 Apr 2021 02:12:51

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-06T19:12:43-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '8ea676f7-2069-46b2-9382-72ecf137b5e5'	System	07 Apr 2021 02:12:51
User entered '06 Apr 2021 19:12:43'	System	07 Apr 2021 02:12:51

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-10T10:40:33-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0faa0587-0144-41d7-8347-2daf104f4145'	System	10 Apr 2021 17:40:42
User entered 'No (N)'	System	10 Apr 2021 17:40:42

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-10T10:40:36-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0faa0587-0144-41d7-8347-2daf104f4145'	System	10 Apr 2021 17:40:42
User entered 'No (N)'	System	10 Apr 2021 17:40:42

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-10T10:40:39-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '0faa0587-0144-41d7-8347-2daf104f4145'	System	10 Apr 2021 17:40:42
User entered '10 Apr 2021 10:40:39'	System	10 Apr 2021 17:40:42

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-18T14:23:48-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3d4730aa-e105-42bb-92b6-863d76562a2d' User entered 'No (N)'	System	18 Apr 2021 21:24:05
	System	18 Apr 2021 21:24:05

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-18T14:23:58-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3d4730aa-e105-42bb-92b6-863d76562a2d'	System	18 Apr 2021 21:24:05
User entered 'No (N)'	System	18 Apr 2021 21:24:05

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-18T14:24:01-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '3d4730aa-e105-42bb-92b6-863d76562a2d'	System	18 Apr 2021 21:24:05
User entered '18 Apr 2021 14:24:01'	System	18 Apr 2021 21:24:05

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-24T00:03:17-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9478c91a-b3b3-429e-a29c-e59c33aff33b' User entered 'No (N)'	System	24 Apr 2021 07:03:26
	System	24 Apr 2021 07:03:26

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-24T00:03:21-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9478c91a-b3b3-429e-a29c-e59c33aff33b'	System	24 Apr 2021 07:03:26
User entered 'No (N)'	System	24 Apr 2021 07:03:26

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-04-24T00:03:24-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '9478c91a-b3b3-429e-a29c-e59c33aff33b' User entered '24 Apr 2021 00:03:24'	System	24 Apr 2021 07:03:26
	System	24 Apr 2021 07:03:26

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-05-02T20:23:20-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7d851bdb-5ebb-415c-ba2b-877323e54062'	System	03 May 2021 03:23:31
User entered 'No (N)'	System	03 May 2021 03:23:31

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-05-02T20:23:24-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7d851bdb-5ebb-415c-ba2b-877323e54062'	System	03 May 2021 03:23:31
User entered 'No (N)'	System	03 May 2021 03:23:31

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-05-02T20:23:27-07:00', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: '7d851bdb-5ebb-415c-ba2b-877323e54062'	System	03 May 2021 03:23:31
User entered '02 May 2021 20:23:27'	System	03 May 2021 03:23:31

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:31:38

US3642024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:31:38
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:31:38

US3642024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:09:46

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:20:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-28T20:59:48', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'fb6be547-c876-4fb4-964c-8d5ca3883d12'	System	01 Mar 2021 05:00:12
User entered 'No (N)'	System	01 Mar 2021 05:00:12

US3642024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:09:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:20:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83F78BC4-4000-472F-B120-DEC3DEA0CDD0)', Time: '2021-02-28T21:00:06', User OID: 'PatientReportedOutcome (US3642024)', ODM File OID: 'fb6be547-c876-4fb4-964c-8d5ca3883d12' User entered '28 Feb 2021 21:00:06'	System	01 Mar 2021 05:00:12
	System	01 Mar 2021 05:00:12

US3642024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:05:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	20 Nov 2020 19:01:53

US3642024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:05:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 09:34:01
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Data are correct. Call made outside of window due to error with study-provided visit calculator' (Site from System).	Benjamin Hull (b) (4) (b) (4)	03 Feb 2021 22:31:28
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Nov 2020 19:01:53
User entered '20 Nov 2020'	Jennifer Morales (b) (4) (b) (4)	20 Nov 2020 19:01:53

US3642024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.		12 Apr 2021 22:05:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	20 Nov 2020 19:01:53

US3642024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:05:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Jennifer Morales (b) (4) (b) (4)	20 Nov 2020 19:01:53

US3642024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
DataPoint Verified.	(b) (4)	12 Apr 2021 22:05:18
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	20 Nov 2020 19:02:32

US3642024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:00:16
User entered 'I'	System	20 Nov 2020 19:02:32

US3642024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:05:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'No (N)'	(b) (4) Colleen McLellan (b) (4) (b) (4)	06 Jan 2021 16:48:04

US3642024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.	(b) (4)	12 Apr 2021 22:05:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Colleen McLellan (b) (4) (b) (4)	06 Jan 2021 16:48:04

US3642024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.	(b) (4)	12 Apr 2021 22:05:45
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Colleen McLellan (b) (4) (b) (4)	06 Jan 2021 16:48:04

US3642024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.	(b) (4)	12 Apr 2021 22:05:45
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:11
Signature has been broken.	(b) (4)	
	Megan Loughran (b) (4)	22 Mar 2021 17:14:43
	(b) (4)	
User entered 'call missed d/t staff error.' reason for change: Data Entry Error	Megan Loughran (b) (4)	22 Mar 2021 17:14:43
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Jan 2021 16:48:04
	(b) (4)	

US3642024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:05:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4) (b) (4)	06 Jan 2021 16:48:08

US3642024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
User entered 'I'	System	06 Jan 2021 16:48:08

US3642024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Feb 2021 19:13:10

US3642024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '01 Feb 2021'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Feb 2021 19:13:10

US3642024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Feb 2021 19:13:10

US3642024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Feb 2021 19:13:10

US3642024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:10
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Feb 2021 19:13:15

US3642024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
User entered 'I'	System	01 Feb 2021 19:13:15

US3642024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Mar 2021 23:39:54

US3642024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '01 Mar 2021'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Mar 2021 23:39:54

US3642024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.	(b) (4)	12 Apr 2021 22:06:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Mar 2021 23:39:54

US3642024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.	(b) (4)	12 Apr 2021 22:06:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered empty.	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Mar 2021 23:39:54

US3642024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
DataPoint Verified.		12 Apr 2021 22:06:50
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	01 Mar 2021 23:40:00

US3642024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:54
User entered 'I'	System	01 Mar 2021 23:40:00

US3642024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:53
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:53

US3642024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:53
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered '23 Mar 2021'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:53

US3642024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[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 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:53
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:53

US3642024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered 'VISIT4'	System	29 Mar 2021 15:17:53

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'No (N)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered empty.	System	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered empty.	System	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered empty.	System	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered empty.	System	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered empty.	System	29 Mar 2021 15:17:59

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20

US3642024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20

US3642024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'No (N)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:04

US3642024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:06:59
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:04

US3642024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:07:03
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:16

US3642024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:07:03
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered '23 Mar 2021'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:16

US3642024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:07:03
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered '14:05'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:16

US3642024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered '23 Mar 2021 14:05'	System	29 Mar 2021 15:18:16

US3642024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
DataPoint Verified.		12 Apr 2021 22:07:07
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:21

US3642024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:20
User entered '1'	System	29 Mar 2021 15:18:21

US3642024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	30 Apr 2021 18:56:42
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	29 Apr 2021 20:03:45
	(b) (4)	

US3642024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	30 Apr 2021 18:56:42
	(b) (4)	
User entered '29 Apr 2021'	Colleen McLellan (b) (4)	29 Apr 2021 20:03:45
	(b) (4)	

US3642024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	30 Apr 2021 18:56:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	29 Apr 2021 20:03:45
	(b) (4)	

US3642024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	30 Apr 2021 18:56:42
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	29 Apr 2021 20:03:45
	(b) (4)	

US3642024

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	30 Apr 2021 18:56:42
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	29 Apr 2021 20:03:50
	(b) (4)	

US3642024

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:03:50

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:33:47

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '19 Jan 2021'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:33:47

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[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 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:26
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:33:47

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 16:33:47

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:07:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '19 Jan 2021'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:21
	(b) (4)	

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[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 20:10:04
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:02
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:49:19

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:21
	(b) (4)	

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:02
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:49:19

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User closed query 'Per CDM:Response noted,however kindly clarify in query response why the date of unblinding is prior to date of informed consent.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 03:33:22
Query 'Per CDM:Response noted,however kindly clarify in query response why the date of unblinding is prior to date of informed consent.Thank you.' answered with 'Data are correct. Subject unblinding occurred prior to date of consent form. PD reported. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	26 Jan 2021 22:30:51
User opened query 'Per CDM:Response noted,however kindly clarify in query response why the date of unblinding is prior to date of informed consent.Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:26:56
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 05:26:40
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Data is correct' (Site from System).	Fanny Delebecque (b) (4) (b) (4)	19 Jan 2021 21:38:29
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	19 Jan 2021 21:38:21
User entered '8 Jan 2021'	Fanny Delebecque (b) (4) (b) (4)	19 Jan 2021 21:38:21

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Placebo (Placebo)'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:21
	(b) (4)	

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:10:48
User entered 'Placebo (Placebo)'	Fanny Delebecque (b) (4)	19 Jan 2021 21:38:21
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:10:48
User entered 'Placebo (Placebo)'	Fanny Delebecque (b) (4)	19 Jan 2021 21:38:21
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:07:30
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:21
	(b) (4)	

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '1'	System	19 Jan 2021 21:38:21

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:09:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'I'	System	19 Jan 2021 21:38:21

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered missing code ND - Not Done.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered missing code ND - Not Done.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	20 Jan 2021 16:34:33
DataPoint set to visible.	System	19 Jan 2021 21:38:21

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered missing code ND - Not Done.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered missing code ND - Not Done.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	20 Jan 2021 16:34:33
DataPoint set to visible.	System	19 Jan 2021 21:38:21

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '19 Jan 2021'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '12:05'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '19 Jan 2021 12:05'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '98.2' F	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '74'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'bpm'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '16'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'breaths/min'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '107'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'mmHg'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 10:57:18
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'BP not clinically significant' (Site from System).	Benjamin Hull (b) (4) (b) (4)	10 Feb 2021 20:06:24
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Jan 2021 16:34:33
User entered '56'	Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'mmHg'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered missing code ND - Not Done.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered missing code ND - Not Done.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered empty.	System	20 Jan 2021 16:34:33
DataPoint set to visible.	System	19 Jan 2021 21:38:21

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '19 Jan 2021'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '13:32'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered '19 Jan 2021 13:32'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '97.7' F	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '63'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'bpm'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '16'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'breaths/min'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.		12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '119'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'mmHg'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:55
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '60'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:28
User entered 'mmHg'	System	20 Jan 2021 16:34:33

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:07:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'No (N)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:07:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:08:08
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:59
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:08:08
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:59
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:08:08
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:59
	(b) (4)	

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'mRNA-1273'	System	19 Jan 2021 21:38:59
DataPoint set to visible.	System	19 Jan 2021 21:38:21

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:08:08
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '19 Jan 2021'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:59
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:08:08
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '12:53'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:59
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '19 Jan 2021 12:53'	System	19 Jan 2021 21:38:59

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:08:08
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:38:59
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:08:08
User entered 'ONCE'	System	19 Jan 2021 21:38:59

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 21:38:59

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:08:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:50

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:08:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '19 Jan 2021'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:50

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:08:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '12:35'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:34:50

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '19 Jan 2021 12:35'	System	20 Jan 2021 16:34:50

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:08:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:35:01

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:46

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:08:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '19 Jan 2021'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:35:01

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:08:36
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered '12:37'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:35:01

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:46

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '19 Jan 2021 12:37'	System	20 Jan 2021 16:35:01

US3642024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:08:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	19 Jan 2021 21:39:06
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '1'	System	19 Jan 2021 21:39:06

US3642024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:07:07
DataPoint Verified.		12 Apr 2021 22:10:11
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:11
Signature has been broken.	(b) (4) Megan Loughran (b) (4)	22 Mar 2021 17:17:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Megan Loughran (b) (4)	22 Mar 2021 17:17:28
User signature succeeded.	(b) (4) Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered 'No (N)'	(b) (4) Lindsey Woronicz (b) (4)	27 Jan 2021 22:13:24

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:07:07
DataPoint Verified.	(b) (4)	12 Apr 2021 22:10:11
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:11
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Mar 2021 17:23:47
User entered '26 Jan 2021' reason for change: Data Entry Error	System	22 Mar 2021 17:23:47
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Megan Loughran (b) (4)	22 Mar 2021 17:23:47
Signature has been broken.	(b) (4)	
User entered '24 Feb 2021' reason for change: Data Entry Error	System	22 Mar 2021 17:17:28
User signature succeeded.	Megan Loughran (b) (4)	22 Mar 2021 17:17:28
User entered empty.	(b) (4)	
	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
	(b) (4)	
	Lindsey Woronicz (b) (4)	27 Jan 2021 22:13:24
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:07:07
DataPoint Verified.	(b) (4)	12 Apr 2021 22:10:11
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:11
Signature has been broken.	(b) (4)	
	Megan Loughran (b) (4)	22 Mar 2021 17:17:28
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Megan Loughran (b) (4)	22 Mar 2021 17:17:28
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
	(b) (4)	
User entered empty.	Lindsey Woronicz (b) (4)	27 Jan 2021 22:13:24
	(b) (4)	

US3642024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:07:07
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Apr 2021 14:17:08
DataPoint Un-verified.	Jennifer Morales (b) (4)	14 Apr 2021 22:32:05
Signature has been broken.	(b) (4) Jennifer Morales (b) (4)	14 Apr 2021 22:32:05
User entered 'MULTIPLE UNSUCCESSFUL ATTEMPTS MADE TO CONTACT PT ON 1/26/21, 1/26/21,1/27/21. EMAIL SENT. PT DID NOT RETURN CALL.' reason for change: Data Entry Error	Jennifer Morales (b) (4) (b) (4)	14 Apr 2021 22:32:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:10:11
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:11
User entered 'MULTIPLE UNSUCCESSFUL ATTEMPTS MADE TO CONTACT PT ON 1/26/21, 1/26/21,1/27/21. EMAIL SENT. PT DID NOT RETURN CONTACT.' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 17:23:47
Signature has been broken.	Megan Loughran (b) (4)	22 Mar 2021 17:17:28
User entered 'multiple unsuccessful attempts made to contact pt on 2/24/21 at 1038, 1347, 1706. email sent. pt did not return contact.' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	22 Mar 2021 17:17:28
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	27 Jan 2021 22:13:24

US3642024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:07:07
DataPoint Verified.		12 Apr 2021 22:10:29
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
	(b) (4)	
User entered 'Yes (Y)'	Lindsey Woronicz (b) (4)	27 Jan 2021 22:13:28

US3642024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:07:07
User entered 'I'	System	27 Jan 2021 22:13:28

US3642024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:07:07
User entered '1'	System	27 Jan 2021 22:13:28
DataPoint set to visible.	System	27 Jan 2021 22:13:28

US3642024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:10:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:03

US3642024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:10:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '17 Feb 2021'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:03

US3642024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[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 20:10:04
DataPoint Verified.		12 Apr 2021 22:10:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:03

US3642024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'OLD29'	System	24 Feb 2021 16:58:03

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '17 Feb 2021'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '13:38'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '17 Feb 2021 13:38'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '98.2' F	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered empty.	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '65'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'bpm'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '17'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'breaths/min'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '108'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'mmHg'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:53:45
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'BP not clinically significant.' (Site from System).	Benjamin Hull (b) (4) (b) (4)	04 Mar 2021 19:15:25
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		24 Feb 2021 16:58:46
User entered '58'	Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'mmHg'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '17 Feb 2021'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '14:58'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '17 Feb 2021 14:58'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '97.6' F	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered empty.	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '59'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'bpm'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '17'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'breaths/min'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '121'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'mmHg'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '63'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:46

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'mmHg'	System	24 Feb 2021 16:58:46

US3642024

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:12
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'No (N)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:56

US3642024

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:12
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered empty.	(b) (4) Son Do (b) (4)	24 Feb 2021 16:58:56

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered empty.	(b) (4) Son Do (b) (4)	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered empty.	(b) (4) Son Do (b) (4)	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'mRNA-1273'	System	24 Feb 2021 16:59:11
DataPoint set to visible.	System	27 Jan 2021 22:13:28

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '17 Feb 2021'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered '14:27'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered '17 Feb 2021 14:27'	System	24 Feb 2021 16:59:11

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Left Arm (LEFT ARM)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:18
User entered 'ONCE'	System	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 16:59:11

US3642024

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
DataPoint Verified.		12 Apr 2021 22:11:23
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	24 Feb 2021 16:59:17

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:04
User entered 'I'	System	24 Feb 2021 16:59:17

US3642024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:05:15
DataPoint Verified.		12 Apr 2021 22:11:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	25 Feb 2021 01:31:52

US3642024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:05:15
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 07:33:43
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'contact made out of window' (Site from System).	Jennifer Morales (b) (4) (b) (4)	01 Mar 2021 23:38:00
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Mar 2021 23:37:44
User entered '01 Mar 2021' reason for change: New Information	Jennifer Morales (b) (4) (b) (4)	01 Mar 2021 23:37:44
User entered '24 Feb 2021'	Jennifer Morales (b) (4) (b) (4)	25 Feb 2021 01:31:52

US3642024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:05:15
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Jennifer Morales (b) (4)	01 Mar 2021 23:37:44
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jennifer Morales (b) (4)	25 Feb 2021 01:31:52
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:05:15
DataPoint Verified.		12 Apr 2021 22:11:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'CONTACT MADE 01mar2021	(b) (4) Jennifer Morales (b) (4)	01 Mar 2021 23:37:44
ATTEMPT 1: 24FEB2021 1038 A	(b) (4)	
ATTEMPT 2: 24FEB2021 1347 P		
ATTEMPT 3 24FEB2021 1706 P NO VM EMAIL SENT' reason for change: New Information		
User entered 'NO CONTACT MADE	Jennifer Morales (b) (4)	25 Feb 2021 01:31:52
ATTEMPT 1: 24FEB2021 1038 A	(b) (4)	
ATTEMPT 2: 24FEB2021 1347 P		
ATTEMPT 3 24FEB2021 1706 P NO VM EMAIL SENT'		

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:05:15
DataPoint Verified.		12 Apr 2021 22:11:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:37:21
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	25 Feb 2021 01:31:58

US3642024

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:05:15
User entered 'I'	System	25 Feb 2021 01:31:58

US3642024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:49
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:39

US3642024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.		12 Apr 2021 22:11:49
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered '23 Mar 2021'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:39

US3642024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:49
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:39

US3642024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
User entered 'OLD57'	System	29 Mar 2021 15:18:39

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.		12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'No (N)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.		12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
User entered empty.	System	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.		12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
User entered empty.	System	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
User entered empty.	System	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
User entered empty.	System	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:52
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
User entered empty.	System	29 Mar 2021 15:18:45

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29

US3642024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29

US3642024

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.		12 Apr 2021 22:11:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'No (N)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:51

US3642024

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:11:56
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered empty.	(b) (4) Son Do (b) (4)	29 Mar 2021 15:18:51

US3642024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:12:02
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:19:09

US3642024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:12:02
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered '23 Mar 2021'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:19:09

US3642024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
DataPoint Verified.	(b) (4)	12 Apr 2021 22:12:02
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:25:03
User entered '14:05'	(b) (4) Son Do (b) (4)	29 Mar 2021 15:19:09

US3642024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:16:29
User entered '23 Mar 2021 14:05'	System	29 Mar 2021 15:19:09

US3642024

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:09:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:05
Signature has been broken.	Megan Loughran (b) (4)	12 Apr 2021 19:52:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Megan Loughran (b) (4)	12 Apr 2021 19:52:03
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 12:48:45

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:16:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:16:00
Data point term sent to Coder	System	12 Apr 2021 19:54:43
User entered 'motor vehicle accident'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User entered empty.	System	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User entered empty.	System	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:54:44
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:04
User closed query 'Per MM: please clarify why this was considered related to IP.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 17:55:54
Query 'Per MM: please clarify why this was considered related to IP.' answered with 'Relationship has been corrected to Not Related. This was a data entry error. Please close the query.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:27:59
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:27:14
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:27:14
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Apr 2021 16:27:14
User opened query 'Per MM: please clarify why this was considered related to IP.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 15:38:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Related (RELATED)'	Megan Loughran (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
DataPoint Verified.	(b) (4)	29 Apr 2021 19:54:44
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:27:32
Signature has been broken.	(b) (4)	26 Apr 2021 16:27:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	26 Apr 2021 16:27:32
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Related (RELATED)'	Megan Loughran (b) (4)	12 Apr 2021 19:54:18
	(b) (4)	

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Apr 2021 19:54:34
User entered '1' reason for change: Data Entry Error	Megan Loughran (b) (4)	12 Apr 2021 19:54:34
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	12 Apr 2021 19:54:18
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Participant had a motorcycle accident on 25SEP2020. He went to the UCSD Emergency room, was evaluated for broken ribs, scapula, and assessed for internal injury. He was transferred to the Scripps hospital trauma unit for additional evaluation, where he was hospitalized in the ICU. He underwent VATS, cryoablation, and plating of his fractures on 27SEP2020, and remained in ICU. On 28SEP2020, he was transferred to regular unit and was discharged on 30SEP2020. During in patient bloodwork, an additional new diagnosis of chronic kidney disease was discovered. Diagnoses from this visit include: Closed fracture of multiple ribs, hemopneumothorax right side, closed fracture of body of right scapula, abrasions of multiple sites (locations unknown), stage 3 Chronic kidney disease, magnesium deficiency, No Bowel movement for 3 days, nausea'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User entered '0'	System	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04
User entered 'I'	System	12 Apr 2021 19:54:18

US3642024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:04

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:53:41
User entered 'USA-US109-2021-mRNA-1273-P301000013'	System	13 Apr 2021 16:51:25
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 16:51:25

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider adjusting event term ,closed fracture of multiple ribs, to include all injuries sustained from motorcycle accident listed in narrative. Consider whether they meet separate event criteria.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:35:42
Query 'PV Query: Please consider adjusting event term ,closed fracture of multiple ribs, to include all injuries sustained from motorcycle accident listed in narrative. Consider whether they meet separate event criteria.' answered with 'Verified per source that all injuries relevant to the motorcycle accident and requires reporting have been reported. Please see AE lines #3-5. ' (Site from Safety).	Nancy Tang (b) (4)	23 Apr 2021 16:50:52
User opened query 'PV Query: Please consider adjusting event term ,closed fracture of multiple ribs, to include all injuries sustained from motorcycle accident listed in narrative. Consider whether they meet separate event criteria.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:12:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Closed fracture of multiple ribs, unspecified - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 12:41:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 12:41:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:11
Data point term sent to Coder	System	12 Apr 2021 20:00:52
User entered 'closed fracture of multiple ribs'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	12 Apr 2021 20:00:34
User entered '11 Jan 2021' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:34
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	12 Apr 2021 20:00:02
User entered '11 Jan 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:54:44
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:04
User closed query 'PV Query: Please update action taken from none to not applicable for the events, closed fracture of multiple ribs and hemopneumothorax, as the subject received both scheduled doses of study drug.' (Site from Safety). Query 'PV Query: Please update action taken from none to not applicable for the events, closed fracture of multiple ribs and hemopneumothorax, as the subject received both scheduled doses of study drug.' answered with 'Not applicable updated per query request.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:35:50
DataPoint Un-verified.	Nancy Tang (b) (4)	23 Apr 2021 16:54:59
Signature has been broken.	Nancy Tang (b) (4)	23 Apr 2021 16:54:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Nancy Tang (b) (4)	23 Apr 2021 16:54:41
User opened query 'PV Query: Please update action taken from none to not applicable for the events, closed fracture of multiple ribs and hemopneumothorax, as the subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:12:33
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4)	12 Apr 2021 20:00:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:00:02

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:36:02
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		26 Apr 2021 13:35:59
User closed query 'PV Query: In narrative, subject was diagnosed with stage 3 kidney disease, magnesium deficiency, and no bowel movement for 3 days. Please determine if any additional diagnoses meet event reporting criteria. If not, please consider adding to medical history.' (Site from Safety).		26 Apr 2021 13:35:55
Query 'PV Query: In narrative, subject was diagnosed with stage 3 kidney disease, magnesium deficiency, and no bowel movement for 3 days. Please determine if any additional diagnoses meet event reporting criteria. If not, please consider adding to medical history.' answered with 'These adverse events have already been reported. Please see log lines 6, 7, and 8. It would be incorrect to add these diagnoses into the medical history since they occurred after the study began. No additional diagnoses meet event reporting criteria. Please close the query.' (Site from Safety).		23 Apr 2021 18:18:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'A rapid COVID-19 test was performed during the hospital admission on 25SEP2020 and showed that COVID-19 was NOT detected. This information is provided in subject's chart under the printed hospitalization records. Please close the query.' (Site from Safety).		23 Apr 2021 18:06:22

US3642024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'All relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added have been sent to Safety_Moderna@iqvia.com. Please close the query.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 18:03:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		22 Apr 2021 18:12:44
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		22 Apr 2021 18:11:49
User opened query 'PV Query: In narrative, subject was diagnosed with stage 3 kidney disease, magnesium deficiency, and no bowel movement for 3 days. Please determine if any additional diagnoses meet event reporting criteria. If not, please consider adding to medical history.' (Site from Safety).		22 Apr 2021 18:11:37
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WANT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4)	12 Apr 2021 20:00:34
reason for change: Data Entry Error User entered empty.	Megan Loughran (b) (4)	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:00:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:55:31
Un-reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:55:00
User entered 'USA-US109-2021-mRNA-1273-P301000013' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 16:55:00
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:54:19
User entered 'USA-US109-2021-mRNA-1273-P301000014'	System	13 Apr 2021 16:54:15
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 16:54:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Traumatic haemothorax, LLT: Hemopneumothorax - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Apr 2021 13:23:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 13:23:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:11
Data point term sent to Coder	System	12 Apr 2021 20:02:32
User entered 'hemopneumothorax right side'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '30 Sep 2020' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:34:40
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 4 (Grade 4)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '30 Sep 2020'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '3'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:35:46
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:04
User closed query 'PV Query: Please update action taken from none to not applicable for the events, closed fracture of multiple ribs and hemopneumothorax, as the subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:36:15
Query 'PV Query: Please update action taken from none to not applicable for the events, closed fracture of multiple ribs and hemopneumothorax, as the subject received both scheduled doses of study drug.' answered with 'Not applicable updated per query request.' (Site from Safety).	Nancy Tang (b) (4)	23 Apr 2021 16:57:56
DataPoint Un-verified.	Nancy Tang (b) (4)	23 Apr 2021 16:57:50
Signature has been broken.	Nancy Tang (b) (4)	23 Apr 2021 16:57:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Nancy Tang (b) (4)	23 Apr 2021 16:57:50
User opened query 'PV Query: Please update action taken from none to not applicable for the events, closed fracture of multiple ribs and hemopneumothorax, as the subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:13:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:01:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:36:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'All relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added have been sent to Safety_Moderna@iqvia.com. Please close the query.' (Site from Safety).		23 Apr 2021 18:02:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		22 Apr 2021 18:13:10
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WANT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4)	12 Apr 2021 20:01:56

US3642024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 20:01:56

US3642024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 20:01:56

US3642024

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 20:01:56

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Scapula fracture, LLT: Closed fracture of scapula - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 12:48:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 12:48:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:11
Data point term sent to Coder	System	12 Apr 2021 20:03:33
User entered 'closed fracture of body of right scapula'	Megan Loughran (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User entered empty.	System	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '11 Jan 2021'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User entered empty.	System	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'l'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WANT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User entered '0'	System	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24
User entered 'I'	System	12 Apr 2021 20:02:47

US3642024

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:24

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Abrasions - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 12:35:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 12:35:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:11
Data point term sent to Coder	System	12 Apr 2021 20:03:33
User entered 'abrasions of multiple sites (locations unknown)'	Megan Loughran (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User entered empty.	System	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '08 Oct 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User entered empty.	System	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'l'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 20:03:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 20:03:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Megan Loughran (b) (4)	12 Apr 2021 20:03:40
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 20:03:27
User entered empty.	Megan Loughran (b) (4)	12 Apr 2021 20:03:27
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WANT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:03:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User entered '0'	System	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26
User entered '1'	System	12 Apr 2021 20:03:27

US3642024

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:26

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
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 stage 3 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:21:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:21:13
Data point term sent to Coder	System	12 Apr 2021 20:04:34
User entered 'stage 3 chronic kidney disease'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

US3642024

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4)	12 Apr 2021 20:04:19
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (6)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 20:04:19

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Absent bowel movement - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:31:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:31:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:11
Data point term sent to Coder	System	12 Apr 2021 20:05:36
User entered 'no bowel movement for 3 days'	Megan Loughran (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '29 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User entered empty.	System	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User entered empty.	System	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'I'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:05:00

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WENT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4)	12 Apr 2021 20:05:00

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User entered '0'	System	12 Apr 2021 20:05:00

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31
User entered 'I'	System	12 Apr 2021 20:05:00

US3642024

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:31

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Magnesium deficiency, LLT: Magnesium deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:21:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:21:38
Data point term sent to Coder	System	12 Apr 2021 20:07:40
User entered 'magnesium deficiency'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User entered empty.	System	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User entered empty.	System	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'l'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WANT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:06:41

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User entered '0'	System	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36
User entered 'I'	System	12 Apr 2021 20:06:41

US3642024

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:36

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:21:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:21:38
Data point term sent to Coder	System	12 Apr 2021 20:07:40
User entered 'nausea'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User entered empty.	System	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User entered empty.	System	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'None (NONE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'l'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:11
User entered 'PARTICIPANT HAD A MOTORCYCLE ACCIDENT ON 25SEP2020. HE WANT TO THE UCSD EMERGENCY ROOM, WAS EVALUATED FOR BROKEN RIBS, SCAPULA, AND ASSESSED FOR INTERNAL INJURY. HE WAS TRANSFERRED TO THE SCRIPPS HOSPITAL TRAUMA UNIT FOR ADDITIONAL EVALUATION, WHERE HE WAS HOSPITALIZED IN THE ICU. HE UNDERWENT VATS, CRYOABLATION, AND PLATING OF HIS FRACTURES ON 27SEP2020, AND REMAINED IN ICU. ON 28SEP2020, HE WAS TRANSFERRED TO REGULAR UNIT AND WAS DISCHARGED ON 30SEP2020. DURING IN PATIENT BLOODWORK, AN ADDITIONAL NEW DIAGNOSIS OF CHRONIC KIDNEY DISEASE WAS DISCOVERED. DIAGNOSES FROM THIS VISIT INCLUDE: CLOSED FRACTURE OF MULTIPLE RIBS, HEMOPNEUMOTHORAX RIGHT SIDE, CLOSED FRACTURE OF BODY OF RIGHT SCAPULA, ABRASIONS OF MULTIPLE SITES (LOCATIONS UNKNOWN), STAGE 3 CHRONIC KIDNEY DISEASE, MAGNESIUM DEFICIENCY, NO BOWEL MOVEMENT FOR 3 DAYS, NAUSEA'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User entered '0'	System	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40
User entered 'I'	System	12 Apr 2021 20:07:32

US3642024

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:56:40

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:09:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:40
DataPoint Verified.		12 Apr 2021 22:12:22
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 12:48:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 13:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:19:51
Data point term sent to Coder	System	31 Aug 2020 13:19:00
User entered 'atorvastatin'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'hyperlipidemia'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '40'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'mg (mg)'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'once daily (QD)'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (ORAL)'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '25 Oct 2019'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 13:18:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 13:20:59
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 13:20:59
Data point term sent to Coder User entered 'flexeril'	System Megan Loughran (b) (4)	31 Aug 2020 13:20:01 31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).		06 Oct 2020 21:02:41
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'corrected' (Site from DM).	Son Do (b) (4)	05 Oct 2020 16:20:41
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:44:09
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	31 Aug 2020 23:54:29
User entered 'back pain'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '5'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'mg (mg)'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'as needed (PRN)'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (ORAL)'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '05 Aug 2020'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:19:29

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE, PRODUCTSYNONYM: NIZORAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 15:28:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:28:37
Data point term sent to Coder	System	31 Aug 2020 13:21:02
User entered 'nizoral 2% shampoo'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User closed query 'Per CDM Re-Query: Please note that Dandruff is still not recorded in the Med Hx page. Please review. Thank you' (Site from DM).		17 Dec 2020 03:58:49
Query 'Per CDM Re-Query: Please note that Dandruff is still not recorded in the Med Hx page. Please review. Thank you' answered with 'added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:09:54
User opened query 'Per CDM Re-Query: Please note that Dandruff is still not recorded in the Med Hx page. Please review. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 21:03:48
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.		06 Oct 2020 21:03:48
' (Site from DM).		
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Son Do (b) (4)	05 Oct 2020 16:21:27
' answered with 'corrected' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	(b) (4), (b) (6)	05 Oct 2020 10:44:35
' (Site from DM).		
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	31 Aug 2020 23:54:29
User entered 'dandruff'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'I'	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Other (OTHER)'	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'application'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'as needed (PRN)'	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Topical (TOPICAL)'	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '24 Jul 2020'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:20:25

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: FENAMATES, PRODUCT: MECLOFENAMATE SODIUM, PRODUCTSYNONYM: MECLOMEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 10:29:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 10:29:46
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	31 Aug 2020 23:54:29
Data point term sent to Coder	System	31 Aug 2020 13:22:03
User entered 'meclomen'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'back pain'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '50'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'mg (mg)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'other (OTHER)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'every 6 hours'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (ORAL)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '12 Aug 2020'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:21:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:17:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:17:54
Data point term sent to Coder Coding entries removed.	System Megan Loughran (b) (4)	16 Dec 2020 19:16:47 16 Dec 2020 19:15:54
User signature succeeded.	(b) (4) Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 13:22:50
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 13:22:50
Data point term sent to Coder User entered 'seroquel'	System Megan Loughran (b) (4)	31 Aug 2020 13:22:03 31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:23:34
User closed query 'Per CDM Re-Query: Please clarify further the correction made, as Sleep is not a medical condition or diagnosis. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 03:59:18
Query 'Per CDM Re-Query: Please clarify further the correction made, as Sleep is not a medical condition or diagnosis. Thank you' answered with 'revised' (Site from DM).	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:59
Signature has been broken.	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:54
User entered 'insomnia' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	16 Dec 2020 19:15:54
User opened query 'Per CDM Re-Query: Please clarify further the correction made, as Sleep is not a medical condition or diagnosis. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 21:05:27
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).		06 Oct 2020 21:05:27
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Son Do (b) (4)	05 Oct 2020 16:21:15
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:45:28
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	31 Aug 2020 23:54:29
User entered 'sleep'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '400'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'mg (mg)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'once daily (QD)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (ORAL)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '02 May 2015'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 13:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE HYDROCHLORIDE, PRODUCTSYNONYM: ZANAFLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 13:23:48
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 13:23:48
Data point term sent to Coder	System	31 Aug 2020 13:23:04
User entered 'zanaflex'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'back pain'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '4'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'mg (mg)'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'three times daily (TID)'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (ORAL)'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '12 Aug 2020'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 13:22:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 14:04:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 14:04:50
Data point term sent to Coder	System	31 Aug 2020 13:24:06
User entered 'effexor'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.'	(b) (4), (b) (6)	06 Oct 2020 21:06:16
(Site from DM).		
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.'	Son Do (b) (4)	05 Oct 2020 16:20:26
' answered with 'corrected' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.'	(b) (4), (b) (6)	05 Oct 2020 10:46:23
(Site from DM).		
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
	(b) (4)	
User entered 'anxiety disorder'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21
	(b) (4)	

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '150'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'mg (mg)'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'once daily (QD)'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (ORAL)'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '14 May 2015'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Yes (Y)'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	Megan Loughran (b) (4)	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 13:23:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.	(b) (4)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 13:25:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:25:54
Data point term sent to Coder	System	31 Aug 2020 13:25:08
User entered 'meloxicam'	Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'back pain'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '15'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'mg (mg)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.	(b) (4)	12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'once daily (QD)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'Oral (ORAL)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '05 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '0'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered '12 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
DataPoint Verified.		12 Apr 2021 22:12:34
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4) (b) (4)	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
User entered '1'	System	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
User entered '1'	System	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:22
User entered '804 (804)'	System	31 Aug 2020 13:24:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
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)	12 Apr 2021 21:23:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:18
Data point term sent to Coder	System	12 Apr 2021 20:27:16
Data point term sent to Coder	System	12 Apr 2021 20:12:51
User entered 'acetaminophen'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula' reason for change:	Megan Loughran (b) (4)	12 Apr 2021 20:26:17
Data Entry Error	(b) (4)	
User entered 'Rib fracture, scapula fracture'	Megan Loughran (b) (4)	12 Apr 2021 20:12:04
	(b) (4)	

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '1000'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'four times daily (QID)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User entered '4'	System	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User entered '1'	System	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:12
User entered '804 (804)'	System	12 Apr 2021 20:12:04

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 11:29:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 11:29:52
Data point term sent to Coder	System	14 Apr 2021 11:13:59
Query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' canceled (Site from System).	Coder Import (b) (4)	14 Apr 2021 11:13:51
User opened query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4)	14 Apr 2021 10:25:42
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:12:51
User entered 'dulcolax'	Megan Loughran (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'prophylaxis for constipation'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '5'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User entered '1'	System	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User entered '1'	System	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User entered '804 (804)'	System	12 Apr 2021 20:12:41

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:52:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	13 Apr 2021 13:52:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:27:16
Data point term sent to Coder	System	12 Apr 2021 20:13:52
User entered 'celebrex'	Megan Loughran (b) (4)	12 Apr 2021 20:13:26
	(b) (4)	

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula' reason for change:	Megan Loughran (b) (4)	12 Apr 2021 20:26:34
Data Entry Error	(b) (4)	
User entered 'Rib fracture, scapula fracture'	Megan Loughran (b) (4)	12 Apr 2021 20:13:26
	(b) (4)	

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '100'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User entered '2'	System	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User entered '1'	System	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:19
User entered '804 (804)'	System	12 Apr 2021 20:13:26

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:44:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:44:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:27:15
Data point term sent to Coder	System	12 Apr 2021 20:14:53
User entered 'gabapentin'	Megan Loughran (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula' reason for change:	Megan Loughran (b) (4)	12 Apr 2021 20:26:52
Data Entry Error	(b) (4)	
User entered 'Rib fracture, scapula fracture'	Megan Loughran (b) (4)	12 Apr 2021 20:14:33
	(b) (4)	

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '300'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'three times daily (TID)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User entered '3'	System	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User entered '1'	System	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:06
User entered '804 (804)'	System	12 Apr 2021 20:14:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 10:53:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:53:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:15:54
User entered 'heparin'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'prophylaxis for blood clot'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '5000'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'IU (IU)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'three times daily (TID)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '29 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User entered '3'	System	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User entered '1'	System	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:08
User entered '804 (804)'	System	12 Apr 2021 20:15:28

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 11:01:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 11:01:42
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:27:15
Data point term sent to Coder	System	12 Apr 2021 20:16:55
User entered 'hydromorphone'	Megan Loughran (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula' reason for change:	Megan Loughran (b) (4)	12 Apr 2021 20:27:13
Data Entry Error	(b) (4)	
User entered 'Rib fracture, scapula fracture'	Megan Loughran (b) (4)	12 Apr 2021 20:16:33
	(b) (4)	

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0.25'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'every 2 hours'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User entered empty.	System	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User entered empty.	System	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User entered empty.	System	12 Apr 2021 20:16:33

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:49:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:49:42
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:17:57
User entered 'Ipratropium-albuterol 0.5-2.5mg/ml nebulizer solution'	Megan Loughran (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'hemopneumothorax'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'm'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '29 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User entered empty.	System	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User entered empty.	System	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User entered empty.	System	12 Apr 2021 20:17:20

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
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) (b) (4)	12 Apr 2021 21:23:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:10
Data point term sent to Coder	System	12 Apr 2021 20:19:03
User entered 'lactated ringers'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Hemopneumothorax, rib fracture, scapula fracture'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '75'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'continuous'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User entered empty.	System	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User entered empty.	System	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:31
User entered empty.	System	12 Apr 2021 20:18:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:49:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:49:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:19:03
User entered 'lactulose'	Megan Loughran (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No bowel movement for 3 days'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '20'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'g (g)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '29 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User entered '2'	System	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User entered '1'	System	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:45
User entered '804 (804)'	System	12 Apr 2021 20:18:52

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDOPATCH [LIDOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:36:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:36:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:21:07
User entered 'Lidopatch 3.6-1.25%'	Megan Loughran (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Closed fracture of multiple ribs'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'I'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'patch'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Transdermal (TRANSDERMAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User entered '1'	System	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User entered '1'	System	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:38
User entered '804 (804)'	System	12 Apr 2021 20:20:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDOPATCH [LIDOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:36:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:36:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:21:07
User entered 'Lidopatch 3.6-1.25%'	Megan Loughran (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Closed fracture of multiple ribs'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '2'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'patch'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Transdermal (TRANSDERMAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User entered '1'	System	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User entered '1'	System	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:42
User entered '804 (804)'	System	12 Apr 2021 20:21:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDOPATCH [LIDOCAINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 14:36:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:36:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:22:09
User entered 'Lidopatch 3.6-1.25%'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Closed fracture of multiple ribs'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '3'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'patch'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Transdermal (TRANSDERMAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User entered '1'	System	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User entered '1'	System	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:43
User entered '804 (804)'	System	12 Apr 2021 20:21:50

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 13:51:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:51:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:23:10
User entered 'magnesium citrate'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'magnesium deficiency'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '296'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User entered '1'	System	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User entered '1'	System	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:52
User entered '804 (804)'	System	12 Apr 2021 20:22:31

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:08:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:08:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
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)	12 Apr 2021 21:23:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:23:13
Data point term sent to Coder	System	12 Apr 2021 20:23:10
User entered 'magnesium sulfate'	Megan Loughran (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'magnesium deficiency'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '4'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'g (g)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User entered '1'	System	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User entered '1'	System	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:53
User entered '804 (804)'	System	12 Apr 2021 20:23:07

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:26:14
User entered 'morphine'	Megan Loughran (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '2'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User entered empty.	System	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User entered empty.	System	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:54
User entered empty.	System	12 Apr 2021 20:25:14

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:26:15
User entered 'morphine'	Megan Loughran (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '4'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User entered empty.	System	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User entered empty.	System	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:18
User entered empty.	System	12 Apr 2021 20:25:58

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:19
Data point term sent to Coder	System	12 Apr 2021 20:28:18
User entered 'zofran'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'nausea'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '4'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'four times daily (QID)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User entered '4'	System	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User entered '1'	System	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:20
User entered '804 (804)'	System	12 Apr 2021 20:28:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:52:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:52:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:29:25
User entered 'oxycodone'	Megan Loughran (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '5'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User entered empty.	System	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User entered empty.	System	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:05
User entered empty.	System	12 Apr 2021 20:28:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:52:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:52:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:29:21
User entered 'oxycodone'	Megan Loughran (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '10'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User entered empty.	System	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User entered empty.	System	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:58
User entered empty.	System	12 Apr 2021 20:29:11

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:52:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:52:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:30:26
User entered 'oxycodone'	Megan Loughran (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'closed fracture of multiple ribs, closed fracture of body of right scapula'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '15'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '29 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User entered empty.	System	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User entered empty.	System	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:09
User entered empty.	System	12 Apr 2021 20:29:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
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: GLYCOLAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:26
Data point term sent to Coder	System	12 Apr 2021 20:30:26
User entered 'glycolax'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No bowel movment for 3 days'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'I'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'packet'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User entered '1'	System	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User entered '1'	System	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:41
User entered '804 (804)'	System	12 Apr 2021 20:30:17

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM; SENNA ALEXANDRINA, PRODUCTSYNONYM: SENOKOT-S - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:28
Data point term sent to Coder	System	12 Apr 2021 20:31:27
User entered 'senokot-s'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No bowel movment for 3 days'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '8.6/50'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User entered '2'	System	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User entered '1'	System	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:44:25
User entered '804 (804)'	System	12 Apr 2021 20:31:12

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 02:05:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 02:05:17
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, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:54:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:54:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:32:29
User entered 'sodium chloride 0.9% solution'	Megan Loughran (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Hemopneumothorax, closed fracture of multiple ribs, closed fracture of body of right scapula'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '75'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'ml/hour'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'other (OTHER)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'continuous'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User entered empty.	System	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User entered empty.	System	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:17
User entered empty.	System	12 Apr 2021 20:32:24

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:56:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:56:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:34:33
User entered 'sodium chloride 3% nebulizer solution'	Megan Loughran (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'hemopneumothorax'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '3'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '29 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User entered empty.	System	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User entered empty.	System	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:19
User entered empty.	System	12 Apr 2021 20:33:51

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
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)	14 Apr 2021 14:33:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:33:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:35:34
User entered 'lidocaine 2%'	Megan Loughran (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '100'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User entered empty.	System	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User entered empty.	System	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:21
User entered empty.	System	12 Apr 2021 20:35:30

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
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)	14 Apr 2021 09:13:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:13:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:36:45
User entered 'propofol'	Megan Loughran (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '200'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User entered empty.	System	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User entered empty.	System	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:28
User entered empty.	System	12 Apr 2021 20:35:59

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
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)	14 Apr 2021 08:57:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:57:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:36:40
User entered 'rocuronium'	Megan Loughran (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '180'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User entered '1'	System	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User entered '1'	System	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:30
User entered '804 (804)'	System	12 Apr 2021 20:36:27

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
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)	13 Apr 2021 13:49:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 13:49:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:37:45
User entered 'cefazolin'	Megan Loughran (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '4'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User entered empty.	System	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User entered empty.	System	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:35
User entered empty.	System	12 Apr 2021 20:36:55

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:09:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 10:09:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:37:45
User entered 'dexamethasone'	Megan Loughran (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '12'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User entered empty.	System	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User entered empty.	System	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:38
User entered empty.	System	12 Apr 2021 20:37:21

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:42:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:38:46
User entered 'metoclopramide'	Megan Loughran (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '10'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User entered empty.	System	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User entered empty.	System	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:48
User entered empty.	System	12 Apr 2021 20:38:23

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:52:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:52:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:39:47
User entered 'phenylephrine'	Megan Loughran (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '2400'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'ug (ug)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User entered empty.	System	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User entered empty.	System	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:50
User entered empty.	System	12 Apr 2021 20:39:10

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
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)	14 Apr 2021 08:51:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:51:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:39:47
User entered 'sugammadex'	Megan Loughran (b) (4)	12 Apr 2021 20:39:38
	(b) (4)	

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '400'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User entered empty.	System	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User entered empty.	System	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:45:52
User entered empty.	System	12 Apr 2021 20:39:38

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:02:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:02:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:40:49
User entered 'zofran'	Megan Loughran (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '8'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User entered empty.	System	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User entered empty.	System	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:00
User entered empty.	System	12 Apr 2021 20:40:01

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
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) (b) (4)	12 Apr 2021 21:23:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:53
Data point term sent to Coder	System	12 Apr 2021 20:40:49
User entered 'lactated ringers'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '7000'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User entered empty.	System	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User entered empty.	System	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:03
User entered empty.	System	12 Apr 2021 20:40:43

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 02:05:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 02:05:17
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, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:54:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:54:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:12:34
Data point term sent to Coder	System	12 Apr 2021 20:41:51
User entered 'sodium chloride 0.9% infusion'	Megan Loughran (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Plating of right ribs 3-7 fractures, Right chest tube placement, evacuation of retained hemothorax, Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '1000'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '0'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:34
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User entered empty.	System	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User entered empty.	System	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:46:05
User entered empty.	System	12 Apr 2021 20:41:16

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:09:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:40
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:48
Signature has been broken.	Megan Loughran (b) (4)	12 Apr 2021 18:33:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Megan Loughran (b) (4)	12 Apr 2021 18:33:33
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:54:29
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	31 Aug 2020 13:24:21

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '27 Sep 2020'	Megan Loughran (b) (4)	12 Apr 2021 20:08:19
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9 '	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:08:19

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Adverse Event (AE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:08:19

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:46

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:08:19

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:01
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:08:47

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:01
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Plating of right ribs 3-7 fractures'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:08:47

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:01
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Adverse Event (AE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:08:47

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:01
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:08:47

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Right chest tube placement'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Adverse Event (AE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:00

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:06
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:00

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:10
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:15

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:10
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Evacuation of retained hemothorax'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:15

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:10
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Adverse Event (AE)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:15

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:10
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:15

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:14
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:30

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:14
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Chest x-ray'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:30

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:14
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:30

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:14
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:30

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:44

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'CT chest, absomen, pelvis'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:44

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:44

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:17
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:44

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:57

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Chest x-ray'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:57

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:57

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:21
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:09:57

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '26 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:08

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Vascular Ult venous duplex lower extremeity complete bilateral'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:08

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:08

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:25
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:08

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '27 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:19

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Chest x-ray'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:19

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:19

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:29
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:19

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:32
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '28 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:29

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:32
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Chest x-ray'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:29

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:32
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:29

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:32
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:29

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:37
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '29 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:38

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:37
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Chest x-ray'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:38

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:37
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:38

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:37
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:38

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:09:46

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:48

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:09:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Chest x-ray'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:48

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:09:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:48

US3642024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:09:46

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:16:41
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:12:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	12 Apr 2021 20:10:48

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'USA-US109-2021-MRNA-1273-P301000013'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:55:00
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Stephen'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Spector'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 13:36:45
DataPoint Verified.		20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'US'	(b) (4) System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 13:37:10
User entered '1'	System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'USA-US109-2021-MRNA-1273-P301000013'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:55:00
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Stephen'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Spector'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 13:36:45
DataPoint Verified.		20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'US'	(b) (4) System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 13:37:10
User entered '1'	System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:09:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered '13/Apr/2021 12:55'	(b) (4) System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:09:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 13:36:45
DataPoint Verified.		20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'USA-US109-2021-MRNA-1273-P301000013'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:55:00
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Yes (Y)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'No (N)'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Stephen'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:43
User entered 'Spector'	System	13 Apr 2021 16:51:25

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 13:36:45
DataPoint Verified.		20 Apr 2021 16:14:36
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'US'	(b) (4) System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 13:37:10
User entered '1'	System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:09:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:55:06
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:04
User entered '26/Apr/2021 13:36'	(b) (4) System	26 Apr 2021 13:37:10

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:09:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:55:06
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:04
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 13:37:10

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'USA-US109-2021-MRNA-1273-P301000014'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Yes (Y)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Yes (Y)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Yes (Y)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Stephen'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Spector'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'US'	(b) (4) System	13 Apr 2021 16:55:52

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'USA-US109-2021-MRNA-1273-P301000014'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Yes (Y)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Yes (Y)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Yes (Y)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'No (N)'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Stephen'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'Spector'	(b) (4) System	13 Apr 2021 16:54:15

US3642024

Folder: SAE USA-US109-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:14:42
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:22
User entered 'US'	(b) (4) System	13 Apr 2021 16:55:52