

US3642035 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:11:03

All time stamps listed in this document are displayed in GMT

US3642035

Form: Participant Creation

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

[Participant ID](#)

US3642035

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

US3642035

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

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

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3642035

Folder: Screening

Form: Demographics

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input 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 23:45:19

Generated On: 10 Jun 2021 09:11:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 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 checked="" type="radio"/>
	Amendment 3 <input 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

US3642035

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

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 02:26:06

Generated On: 10 Jun 2021 09:11:03

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 21:03:06

Generated On: 10 Jun 2021 09:11:03

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 21:03:06

Generated On: 10 Jun 2021 09:11:03

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 21:03:06

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 21:03:06

Generated On: 10 Jun 2021 09:11:03

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 21:03:06

Generated On: 10 Jun 2021 09:11:03

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3642035

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:00 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:00
Height (<i>xxx.x</i>)	151.2 cm
Weight (<i>xxx.x</i>)	57.0 kg
BMI (<i>xxx.x</i>)	24.93281 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) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 21:03:06

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*) 28 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1999

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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) 13 Feb 2021 02:26:06

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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 23:45:19

Generated On: 10 Jun 2021 09:11:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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 02:26:06

Generated On: 10 Jun 2021 09:11:03

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 188806

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 02:26:06

Generated On: 10 Jun 2021 09:11:03

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 02:26:06

Generated On: 10 Jun 2021 09:11:03

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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)	28 AUG 2020
Time of assessment (00:00-23:59)	17:25 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:25
Temperature (xxx.x)	97.8 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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 23:45:19

Generated On: 10 Jun 2021 09:11:03

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 16:47 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 16:47

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) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	15:50 (24 HR)
Collection date and time (derived)	28 AUG 2020 15:50

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:00	28 AUG 2020 16:00
Nasopharyngeal Swab 2	No		

US3642035

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

28 AUG 2020 17:13

PC Open Date & Time

28 AUG 2020 17:07

PC Close Date & Time

28 AUG 2020 19:37

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 97.1 °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 21:54
PC Open Date & Time	28 AUG 2020 20:32
PC Close Date & Time	29 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:43

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 17:43

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

98.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 SEP 2020 08:31

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	01 SEP 2020 21:49
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

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

99.1 °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 SEP 2020 20:26

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

28 AUG 2020 17:13

PC Open Date & Time

28 AUG 2020 17:07

PC Close Date & Time

28 AUG 2020 19:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

28 AUG 2020 21:54

PC Open Date & Time

28 AUG 2020 20:32

PC Close Date & Time

29 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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 12:43

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

30 AUG 2020 17:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

01 SEP 2020 08:31

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

01 SEP 2020 21:50

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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

02 SEP 2020 20:26

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 17:14
PC Open Date & Time	28 AUG 2020 17:07
PC Close Date & Time	28 AUG 2020 19:37

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 21:55
PC Open Date & Time	28 AUG 2020 20:32
PC Close Date & Time	29 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:44
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

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)

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:42
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

		Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 08:32	
PC Open Date & Time	31 AUG 2020 12:00	
PC Close Date & Time	01 SEP 2020 11:59	

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

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)

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US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

		Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 21:50	
PC Open Date & Time	01 SEP 2020 12:00	
PC Close Date & Time	02 SEP 2020 11:59	

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

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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US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:26
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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)	25 SEP 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 15:09
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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)	25 SEP 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 17:10
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3642035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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) 25 SEP 2020

What was the treatment time? (00:00-23:59) 16:40 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 16:40

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

US3642035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

16:00 (24 HR)

Collection date and time (derived)

25 SEP 2020 16:00

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:03	25 SEP 2020 16:03
Nasopharyngeal Swab 2	No		

US3642035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 17:03

PC Open Date & Time

25 SEP 2020 17:00

PC Close Date & Time

25 SEP 2020 19:30

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp	25 SEP 2020 20:28
PC Open Date & Time	25 SEP 2020 20:25
PC Close Date & Time	26 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 20:47

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

98.0 °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 SEP 2020 19:49

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

28 SEP 2020 21:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

98.2 °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

29 SEP 2020 20:39

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 09:35

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 20:17

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

25 SEP 2020 17:03

PC Open Date & Time

25 SEP 2020 17:00

PC Close Date & Time

25 SEP 2020 19:30

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

25 SEP 2020 20:29

PC Open Date & Time

25 SEP 2020 20:25

PC Close Date & Time

26 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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

26 SEP 2020 20:47

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

27 SEP 2020 19:50

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

28 SEP 2020 21:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

29 SEP 2020 20:40

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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 OCT 2020 09:35

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

01 OCT 2020 20:17

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 17:04
PC Open Date & Time	25 SEP 2020 17:00
PC Close Date & Time	25 SEP 2020 19:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 20:29
PC Open Date & Time	25 SEP 2020 20:25
PC Close Date & Time	26 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 20:48
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

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 ☒

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:50
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

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 ☒

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 21:01
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

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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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 20:40
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 09:36
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 ☒

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:18
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3642035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:54 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 13:54
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	45 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3642035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

14:45 (24 HR)

Collection date and time (derived)

26 OCT 2020 14:45

US3642035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 OCT 2020 12:33:12
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

06 NOV 2020 22:07:50

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 02:03:21
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	24 DEC 2020 23:59
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US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 17:30:53

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 11:59:44

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

24 JAN 2021 06:11:34

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

01 FEB 2021 18:34:31

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 12:21:01
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 FEB 2021 08:00:33
Patient Cloud Open Date & Time	14 FEB 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
138 of 3098	

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

21 FEB 2021 12:25:43

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

01 MAR 2021 09:04:27

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

07 MAR 2021 06:24:34

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

14 MAR 2021 17:26:07

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

21 MAR 2021 13:26:20

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

28 MAR 2021 06:11:55

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 09:43:20
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

11 APR 2021 06:13:24

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 11:54:40

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

25 APR 2021 15:37:47

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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="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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Patient Cloud Open Date & Time	03 OCT 2021 00:01
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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°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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 ☐

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Patient Cloud Open Date & Time	15 MAY 2022 00:01
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Patient Cloud Close Date & Time	19 MAY 2022 23:59
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US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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="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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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 <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"/>

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3642035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:11:03

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 00:33:56

US3642035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3642035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

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.

US3642035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 20:48:38

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 20:48:38

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 20:48:38

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642035

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

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>

US3642035

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3642035

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:26:05

Generated On: 10 Jun 2021 09:11:03

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3642035

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 02:10:42

Generated On: 10 Jun 2021 09:11:03

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	08 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

US3642035

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3642035

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

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)	14 JAN 2021
Time of assessment (00:00-23:59)	15:31 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:31
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3642035

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

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)	14 JAN 2021
Time of assessment (00:00-23:59)	17:24 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 17:24
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3642035

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

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:26:05

Generated On: 10 Jun 2021 09:11:03

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.

US3642035

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

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:26:05

Generated On: 10 Jun 2021 09:11:03

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 16:50 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 16:50

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

US3642035

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:26:05

Generated On: 10 Jun 2021 09:11:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

16:25 (24 HR)

Collection date and time (derived)

14 JAN 2021 16:25

US3642035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 02:26:05

Generated On: 10 Jun 2021 09:11:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	16:29
Collection Date and Time (derived)	14 JAN 2021 16:29

US3642035

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

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:05

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:26:06

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:02:42

Generated On: 10 Jun 2021 09:11:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	13:28 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 13:28
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:18 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:18
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3642035

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:02:42

Generated On: 10 Jun 2021 09:11:03

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.

US3642035

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:02:41

Generated On: 10 Jun 2021 09:11:03

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 14:40

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

US3642035

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:02:41

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:02:42

Generated On: 10 Jun 2021 09:11:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642035

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:02:42

Generated On: 10 Jun 2021 09:11:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642035

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 02:10:42

Generated On: 10 Jun 2021 09:11:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 02:10:42

Generated On: 10 Jun 2021 09:11:03

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) _____

US3642035

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 02:10:42

Generated On: 10 Jun 2021 09:11:03

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.

US3642035

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Mar 2021 02:10:42

Generated On: 10 Jun 2021 09:11:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 MAR 2021

Collection time (00:00-23:59)

15:43 (24 HR)

Collection date and time (derived)

10 MAR 2021 15:43

US3642035

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 02:25:45

Generated On: 10 Jun 2021 09:11:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3642035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

AEID

Adverse event

FLANK PAIN (LEFT)

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

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	

US3642035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

SUBJECT REPORTS 10/10 LEFT
FLANK/LOWER BACK AND
WENT TO ED RULED OUT
KIDNEY STONE, NO
DISSECTION, ASSUMED IT WAS
MUSCLE STRAIN, IMPROVED
TO 2/10 ABOUT 24 HOURS
LATER. ALL LABS, CHEST
XRAY NORMAL. COMPLETELY
BACK TO NORMAL AT 36
HOURS. SUBJECT WILL
CONTINUE TO REMAIN ON
STUDY.

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)	

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

AEID	
Adverse event	DEHYDRATION
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)	31 AUG 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)	31 AUG 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 (2)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

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	WHILE IN ED FOR FLANK PAIN, CLINICIAN OBSERVED MILD DEHYDRATION IN PT. TREATED W/ IV FLUIDS. PT RECOVERED PRIOR TO DISCHARGE W/O SEQUELLAE
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

AEID	
Adverse event	OSTEOPENIA
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)	03 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

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 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	PT DIAGNOSED W/ OSTEOPENIA BY PMD. ONGOING AT THIS TIME. TREATED W/ FOSAMAX.
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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

AEID	USA-US109-2020-MRNA-1273-P30 1000008
Adverse event	WORSENING OSTEOARTHRITIS LEFT HIP
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)	10 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)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	13 OCT 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 (4)

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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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

PATIENT UNDERWENT TOTAL
LEFT HIP REPLACEMENT FOR
WORSENING OSTEOARTHRITIS
OF THE LEFT HIP ON
12OCT2020. SHE HAD A COVID
TEST ON 11OCT2020 PRIOR TO
HER PROCEDURE AND WAS
NEGATIVE. SHE WAS
HOSPITALIZED OVERNIGHT
POST-PROCEDURE. SHE HAS
MADE A FULL RECOVERY AND
WILL REMAIN ON STUDY.

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

AEID

Adverse event

MUSCLE SPASMS (LEFT BACK)

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 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

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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 (5)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

SUBJECT REPORTS 10/10 LEFT FLANK PAIN AND WENT TO ED TO RULE OUT KIDNEY STONE. NO DISSECTION FOUND AND IT WAS ASSUMED TO BE MUSCLE STRAIN D/T LIFTING HEAVY ITEMS WHILE HELPING HER SISTER MOVE. SHE EXPERIENCED LEFT SIDED MUSCLE SPASMS IN HER BACK AND NAUSEA WHILE IN THE ED. ALL LABS, CXR, CHEST CT, AND ABD/PELVIC CT WNL. SHE REPORTS BEING BACK TO BASELINE WITHIN 36 HOURS. SHE WILL REMAIN ON STUDY.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

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)	31 AUG 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)	03 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 (6)

Data signed: (b) (4) 26 Mar 2021 21:15:32

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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	

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

SUBJECT REPORTS 10/10 LEFT FLANK PAIN AND WENT TO ED TO RULE OUT KIDNEY STONE. NO DISSECTION FOUND AND IT WAS ASSUMED TO BE MUSCLE STRAIN D/T LIFTING HEAVY ITEMS WHILE HELPING HER SISTER MOVE. SHE EXPERIENCED LEFT SIDED MUSCLE SPASMS IN HER BACK AND NAUSEA WHILE IN THE ED. ALL LABS, CXR, CHEST CT, AND ABD/PELVIC CT WNL. SHE REPORTS BEING BACK TO BASELINE WITHIN 36 HOURS. SHE WILL REMAIN ON STUDY.

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) 13 Feb 2021 02:25:45

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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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILATION

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 (1)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 23:53:43

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication METROPOLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILATION,
HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 23:53:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication CALCIUM WITH VITAMIN D
SUPPLEMENT

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1200/1600

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

If dose unit is Other, specify MG/IU FOR CALCIUM + D

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 (5)

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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)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 OCT 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 (6)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
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 (7)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication GLUCOSAMINE SULFATE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 3000

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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication CANABREX (PALMITIC ACID
MONO-ETHANOLAMIDE)

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2

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

If dose unit is Other, specify GUMMY BEARS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
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 (10)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication CALCIUM W/ VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 600/800

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

If dose unit is Other, specify MG/IU

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS LEFT HIP

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 (12)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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 OCT 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 (13)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication ONDANSETRON HCL

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 (13)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)		31 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)		31 AUG 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 (14)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication FENTANYL CITRATE

Prophylaxis Yes ☐
No ☒

Indication PAIN (LEFT FLANK)

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)	31 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)		31 AUG 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication DEHYDRATION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)		31 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)		31 AUG 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 (16)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication IOHEXOL 350MG/ML

Prophylaxis Yes ☐
No ☒

Indication CONTRAST FOR CHEST CT (AE
LOG LINE 1)

Dose per administration 35000

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 (16)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)		31 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)		31 AUG 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication LIDOCAINE 5% PATCH

Prophylaxis Yes ☐
No ☒

Indication PAIN LEFT FLANK

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 ☒
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)		31 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) 31 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication DIAZEPAM

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASM

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 (18)

Data signed: (b) (4) 19 Mar 2021 23:53:43

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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 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)		31 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)		31 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication KETOROLAC TROMETHAMINE

Prophylaxis Yes ☐
No ☒

Indication PAIN LEFT FLANK

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 (19)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)		31 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)		31 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication PHENERGAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)		31 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)		31 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication PAIN LEFT FLANK

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)	01 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)		01 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 (22)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication PAIN LEFT FLANK

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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) 01 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 (23)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication FOSAMAX

Prophylaxis Yes ☐
No ☒

Indication OSTEOGENON

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR FLU

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input checked="" 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)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 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 (26)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP REPLACEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 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 OCT 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

Dose per administration 160

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 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 (30)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication RECORONIUM

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication INTRA-OP INFECTION
PROPHYLAXIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 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 (32)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication SUGAMMADEX

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP REPLACEMENT

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 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 (36)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication TRANEXAMIC ACID

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

Dose per administration 1000

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 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 Mar 2021 23:53:43

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Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication TOTAL LEFT HIP
REPLACEMENT

Dose per administration 66.12

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 ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP REPLACEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 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 OCT 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 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication ACETAMINOPHEN RAPID
RELEASE GELCAP

Prophylaxis Yes ☐
No ☒

Indication HIP SURGERY - PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication HIP SURGERY, PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 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 (41)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication HIP SURGERY

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 (41)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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 OCT 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication HIP SURGERY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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 OCT 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 OCT 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 (43)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication SENOKOT-S

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR STOOL
SOFTENING DURING OPIOD
USE

Dose per administration 17.2/100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 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 OCT 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 (44)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication DEXTROSE 5% SODIUM
CHLORIDE 0.9% INFUSION

Prophylaxis Yes ☐
No ☒

Indication HIP SURGERY

Dose per administration 75

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication HIP SURGERY, PAIN

Dose per administration .25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 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 OCT 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 (46)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication HIP SURGERY, PAIN

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 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 OCT 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 (47)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN, HIP

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 (47)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 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 (48)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN, HIP

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

EVERY 6 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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 OCT 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 (49)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication SENOKOT-S

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
CONSTIPATION D/T OPIOD
PRESCRIPTION

Dose per administration 17.2/100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN, HIP

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 (50)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 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"/>

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN, HIP

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 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"/>

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN, HIP

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	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 OCT 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR FLU

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 19 Mar 2021 23:53:43

Generated On: 10 Jun 2021 09:11:03

	Intramuscular	<input checked="" 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)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 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"/>

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 02:25:45

Generated On: 10 Jun 2021 09:11:03

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Mar 2021 01:38:04

Generated On: 10 Jun 2021 09:11:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 AUG 2020	CTA CHEST	Diagnostic	
31 AUG 2020	CTA ABDOMEN AND PELVIS	Diagnostic	
31 AUG 2020	EKG	Diagnostic	
31 AUG 2020	CHEST XRAY	Diagnostic	
12 OCT 2020	TOTAL HIP REPLACEMENT, LEFT	Adverse Event	

US3642035

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

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

US3642035

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 31 Aug 2020 23:45:19

Generated On: 10 Jun 2021 09:11:03

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"/>

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

SAEID	USA-US109-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

SAEID	USA-US109-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	21/DEC/2020 09:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

SAEID	USA-US109-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	22/FEB/2021 16:29
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

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 21:15:32

Generated On: 10 Jun 2021 09:11:03

SAEID	USA-US109-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	26/MAR/2021 11:46
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.	True

Audit

US3642035 (Prod: University of California San Diego)

US3642035

Form: Participant Creation

Generated On: 10 Jun 2021 09:11:03

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:52:11
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'US3642035'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 22:29:23

US3642035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4)	29 Oct 2020 03:43:52
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'completed' (Site from DM).	Son Do (b) (4)	28 Oct 2020 15:12:00
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 21:55:49
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4)	04 Sep 2020 11:37:54
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
	(b) (4)	
User entered 'Yes (Y)'	Fanny Delebecque (b) (4)	29 Aug 2020 00:03:46
	(b) (4)	

US3642035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:55:49
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 22:29:24

US3642035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[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 00:17:04
DataPoint Verified.	(b) (4)	23 Oct 2020 21:55:49
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Clinic (Clinic)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:46
	(b) (4)	

US3642035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'SCRN'	System	29 Aug 2020 00:03:46

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 22:29:25

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '71'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'YEARS'	System	29 Aug 2020 00:04:15

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '71'	System	29 Aug 2020 00:04:29

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Female (F)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'l'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '0'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '0'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '0'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '0'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '0'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered empty.	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '0'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:03

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:08
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '0'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:15
	(b) (4)	

US3642035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '28 Aug 2020'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:29
	(b) (4)	

US3642035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'Aug 2020'	System	29 Aug 2020 00:04:29

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '2020'	System	29 Aug 2020 00:04:29

US3642035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Amendment 2 (2)'	(b) (4) Fanny Delebecque (b) (4) (b) (4)	29 Aug 2020 00:04:29

US3642035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:29
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered empty.	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:29
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered empty.	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:29
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.	(b) (4)	23 Oct 2020 21:56:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'No (N)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:29
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		23 Oct 2020 21:56:29
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 22:29:24

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:11:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'I'	System	29 Aug 2020 00:04:39

US3642035

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.	(b) (4)	23 Oct 2020 21:56:36
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:04:39
	(b) (4)	

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Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:11:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:56:51
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:35:50

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:01:58
Query 'Per MM, please also confirm if this condition is still ongoing, if not please provide the end date. ' canceled (Site from DM).		21 Sep 2020 19:21:19
User opened query 'Per MM, please also confirm if this condition is still ongoing, if not please provide the end date. ' (Site from DM).		21 Sep 2020 19:20:44
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
Data point term sent to Coder	System	01 Sep 2020 06:37:06
User entered 'Atrial fibrillation'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:00
User entered 'UN May 2018'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:52:57
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:02:01
User closed query 'Per MM, please also confirm if this condition is still ongoing, if not please provide the end date. ' (Site from DM).		29 Sep 2020 14:33:15
Query 'Per MM, please also confirm if this condition is still ongoing, if not please provide the end date. ' answered with 'still ongoing' (Site from DM).	Son Do (b) (4)	28 Sep 2020 16:46:38
User opened query 'Per MM, please also confirm if this condition is still ongoing, if not please provide the end date. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:21:16
User entered 'Yes (Y)'	Megan Loughran (b) (4)	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:51:55
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:51:57
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'May 2018'	System	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '2018'	System	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	01 Sep 2020 06:36:18

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:01:50
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:37:48
Data point term sent to Coder	System	01 Sep 2020 06:37:08
User entered 'hyperlipidemia'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:01:52
User entered 'UN May 2018'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:52:26
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:01:54
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:52:28
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:52:29
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'May 2018'	System	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '2018'	System	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	01 Sep 2020 06:36:48

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:52:42
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable' (Site from DM).		04 Nov 2020 06:28:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 18:51:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 18:51:23
Data point term sent to Coder	System	03 Nov 2020 18:51:00
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable' answered with 'added' (Site from DM).	Megan Loughran (b) (4)	03 Nov 2020 18:50:58
DataPoint Un-verified.	Megan Loughran (b) (4)	03 Nov 2020 18:50:54
Coding entries removed.	Megan Loughran (b) (4)	03 Nov 2020 18:50:54
User entered 'osteoARTHRITIS' reason for change:	Megan Loughran (b) (4)	03 Nov 2020 18:50:54
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 21:59:16
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable' (Site from DM).		21 Oct 2020 16:05:27

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 16:48:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 16:48:40
Data point term sent to Coder	System	28 Sep 2020 16:47:46
User entered 'arthritis'	Son Do (b) (4)	28 Sep 2020 16:47:39

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User closed query 'Per source start date is documented as Nov 2018. Please reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:52:53
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:52:51
Query 'Per source start date is documented as Nov 2018. Please reconcile. ' answered with 'added' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:51:01
User entered 'UN Nov 2018' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:50:54
User opened query 'Per source start date is documented as Nov 2018. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 22:00:18
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:47:39

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:52:55
User entered '0' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:50:54
User entered '1'	(b) (4) Son Do (b) (4)	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:59:18
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:52:57
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:52:59
User entered '0'	Son Do (b) (4)	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'Nov 2018'	System	03 Nov 2020 18:50:54
User entered empty.	System	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '2018'	System	03 Nov 2020 18:50:54
User entered empty.	System	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	28 Sep 2020 16:47:39

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:59:07
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:49:43
Data point term sent to Coder	System	28 Sep 2020 16:48:48
User entered 'migraines'	Son Do (b) (4)	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User closed query 'Per source start 'year' is documented. Please check and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:53:26
Query 'Per source start 'year' is documented. Please check and reconcile. ' answered with 'added' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:51:23
User entered 'UN UNK 1980' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:51:18
User opened query 'Per source start 'year' is documented. Please check and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 21:58:59
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:30
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	03 Nov 2020 18:51:26
User entered '0' reason for change: Data Entry Error Megan Loughran	(b) (4)	03 Nov 2020 18:51:26
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	03 Nov 2020 18:51:18
User entered '1'	Son Do (b) (4)	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:59:09
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:32
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:34
User entered '0'	Son Do (b) (4)	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'Jan 1980'	System	03 Nov 2020 18:51:18
User entered empty.	System	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '1980'	System	03 Nov 2020 18:51:18
User entered empty.	System	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	28 Sep 2020 16:47:49

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:47
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:53:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:53:23
Data point term sent to Coder	System	03 Nov 2020 18:52:00
User entered 'postmenopausal'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.	(b) (4)	25 Feb 2021 23:43:21
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:03:06
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Son Do (b) (4)	16 Feb 2021 16:45:07
User entered 'UN UNK 1999' reason for change:	Son Do (b) (4)	16 Feb 2021 16:45:07
Data Entry Error	Son Do (b) (4)	16 Feb 2021 16:45:07
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:53:47
User entered empty.	(b) (4)	
	Megan Loughran (b) (4)	03 Nov 2020 18:51:42
	(b) (4)	

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.	(b) (4)	25 Feb 2021 23:43:23
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:03:06
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Son Do (b) (4)	16 Feb 2021 16:45:07
User entered '0' reason for change: Data Entry Error	Son Do (b) (4)	16 Feb 2021 16:45:07
User signature succeeded.	Son Do (b) (4)	16 Feb 2021 16:45:07
	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:53:47
	(b) (4)	
User entered '1'	Megan Loughran (b) (4)	03 Nov 2020 18:51:42
	(b) (4)	

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:47
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:47
User entered empty.	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:53:47
User entered '0'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'Jan 1999'	System	16 Feb 2021 16:45:07
User entered empty.	System	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '1999'	System	16 Feb 2021 16:45:07
User entered empty.	System	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered empty.	System	03 Nov 2020 18:51:42

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered '28 Aug 2020'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered '15:00'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '28 Aug 2020 15:00'	System	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered '151.2' cm	Megan Loughran (b) (4)	01 Sep 2020 06:39:02
DataPoint set to visible.	(b) (4) System	29 Aug 2020 00:04:39

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered '57.0' kg	Megan Loughran (b) (4)	01 Sep 2020 06:39:02
DataPoint set to visible.	(b) (4) System	29 Aug 2020 00:04:39

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered '24.93281'	System	01 Sep 2020 06:39:02
DataPoint set to visible.	System	29 Aug 2020 00:04:39

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'kg/m2'	System	01 Sep 2020 06:39:02
DataPoint set to visible.	System	29 Aug 2020 00:04:39

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User closed query 'Per CDM: Response noted. However, Please also keep the Unit blank for Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 04:33:20
Query 'Per CDM: Response noted. However, Please also keep the Unit blank for Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure data-fields. Thank you.' answered with 'all info deleted; database does not allow further editing to make the fields blank.' (Site from DM).	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:46:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:02:50
User opened query 'Per CDM: Response noted. However, Please also keep the Unit blank for Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure data-fields. Thank you.' (Site from DM).		29 Sep 2020 12:56:01
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).		29 Sep 2020 12:56:01
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)	28 Sep 2020 16:45:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Sep 2020 16:45:06

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
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). User entered '97.8' F	(b) (4), (b) (6) Megan Loughran (b) (4) (b) (4)	09 Sep 2020 15:17:26 01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered empty; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:45:06
User entered 'Oral (Oral)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:45:06
User entered '56'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'bpm'	System	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:45:06
User entered '14'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'breaths/min'	System	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:45:06
User entered '136'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'mmHg'	System	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:02:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:45:06
User entered '67'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User entered 'mmHg'	System	01 Sep 2020 06:39:02

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04

US3642035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04

US3642035

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:03:37
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:12

US3642035

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:03:37
User entered '28 Aug 2020'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:12

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:10
User entered '28 Aug 2020'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:45

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:10
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:45

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 06:30:37
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:05:30
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:04:10
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).		09 Oct 2020 00:39:47
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:45

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:10
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:45

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:10
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:45

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:10
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:39:45

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.	(b) (4)	25 Feb 2021 23:43:37
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:03:06
DataPoint Un-verified.	(b) (4)	
Son Do	(b) (4)	16 Feb 2021 16:45:33
Signature has been broken.	Son Do (b) (4)	16 Feb 2021 16:45:33
User entered 'UN UNK 1999' reason for change:	Son Do (b) (4)	16 Feb 2021 16:45:33
Data Entry Error		
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:04:10
	(b) (4)	
User entered empty.	Megan Loughran (b) (4)	01 Sep 2020 06:39:45
	(b) (4)	

US3642035

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:11:03

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
DataPoint Verified.		25 Feb 2021 23:43:35
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:03:06
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Son Do (b) (4)	16 Feb 2021 16:45:33
User entered '0' reason for change: Data Entry Error	Son Do (b) (4)	16 Feb 2021 16:45:33
User signature succeeded.	Son Do (b) (4)	16 Feb 2021 16:45:33
	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:04:10
User entered '1'	Megan Loughran (b) (4)	01 Sep 2020 06:39:45
	(b) (4)	

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '0'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

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 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered 'I'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '0'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:17:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:04:39
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:40:29

US3642035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:04:53
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:33
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:04:53
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '28 Aug 2020'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:33
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:04:53
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Clinic (Clinic)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:33
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'VISIT1'	System	29 Aug 2020 00:03:33

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 22:34:16

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '188806'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 22:34:16

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 22:34:16

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
	(b) (4)	
User entered 'No (N)'	Fanny Delebecque (b) (4)	29 Aug 2020 00:03:17
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'No (N)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:17
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'No (N)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:17
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'No (N)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:17
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:05:23
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'No (N)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:03:17
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:03

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:23
User entered 'No (N)'	Son Do (b) (4)	28 Sep 2020 16:45:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:49:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:34:45

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:05:32
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).		29 Sep 2020 04:15:35
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)	28 Sep 2020 16:48:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:48:31
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 15:17:12
User entered '151.2' cm	Megan Loughran (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:48:31
User entered '57.0' kg	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:05:32
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).		29 Sep 2020 04:15:35
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)	28 Sep 2020 16:48:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:48:31
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 15:17:12
User entered '151.2' cm	Megan Loughran (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:48:31
User entered '57.0' kg	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Pre-Dose (PREDOSE)'	Megan Loughran (b) (4)	01 Sep 2020 06:41:55
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:42
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:45
User entered '28 Aug 2020'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:47
User entered '15:00'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '28 Aug 2020 15:00'	System	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:50
User entered '97.8' F	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:51
User entered 'Oral (Oral)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:55:42
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:53
User entered '56'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'bpm'	System	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:55
User entered '14'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'breaths/min'	System	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:58
User entered '136'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:59
User entered '67'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:05:32
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).		29 Sep 2020 04:15:35
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)	28 Sep 2020 16:48:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:48:31
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 15:17:12
User entered '151.2' cm	Megan Loughran (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:05:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Son Do (b) (4)	28 Sep 2020 16:48:31
User entered '57.0' kg	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:41:55

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Post-Dose (POSTDOSE)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
DataPoint Un-verified.	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Megan Loughran (b) (4)	03 Nov 2020 18:47:16
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:06:15
User entered 'No (N)'	Megan Loughran (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered '28 Aug 2020' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 22:16:41
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of -82 minutes. Please review and update or provide a clarification. Thank you' (Site from DM).		20 Nov 2020 08:53:49
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of -82 minutes. Please review and update or provide a clarification. Thank you' answered with 'time transcribed incorrectly. correct time 1725' (Site from DM).	Colleen McLellan (b) (4)	19 Nov 2020 22:06:58
DataPoint Un-verified.	(b) (4)	
	Colleen McLellan (b) (4)	19 Nov 2020 22:06:21
User entered '17:25' reason for change: Data Entry Error	(b) (4)	
	Colleen McLellan (b) (4)	19 Nov 2020 22:06:21
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. But time difference is of -82 minutes. Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:14:53
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered '15:25' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4)	
	Megan Loughran (b) (4)	01 Sep 2020 06:42:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '28 Aug 2020 17:25'	System	19 Nov 2020 22:06:21
User entered '28 Aug 2020 15:25'	System	03 Nov 2020 18:47:16
User entered empty.	System	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered '97.8' F reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered '59' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:42:01
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'bpm'	System	03 Nov 2020 18:47:16
User entered empty.	System	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered '16' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:42:01
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'breaths/min'	System	03 Nov 2020 18:47:16
User entered empty.	System	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered '128' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	03 Nov 2020 18:47:16
User entered empty.	System	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:12
User entered '68' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 18:47:16
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	03 Nov 2020 18:47:16
User entered empty.	System	01 Sep 2020 06:42:01

US3642035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:34
User closed query 'Per eCRF completion guidelines for a combo screen/day 1 visit, response here is 'no'. Please complete this eCRF per the completion guidelines.' (Site from CRA).		06 Nov 2020 19:58:30
Query 'Per eCRF completion guidelines for a combo screen/day 1 visit, response here is 'no'. Please complete this eCRF per the completion guidelines.' answered with 'revised' (Site from CRA).	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:06:15
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	03 Nov 2020 19:06:11
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	03 Nov 2020 19:06:01
DataPoint Un-verified.	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:06:01
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:06:01
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:07:14
User opened query 'Per eCRF completion guidelines for a combo screen/day 1 visit, response here is 'no'. Please complete this eCRF per the completion guidelines.' (Site from CRA).		23 Oct 2020 22:07:12
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:12

US3642035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:58:34
DataPoint Un-verified.	Megan Loughran (b) (4)	03 Nov 2020 19:06:11
User entered empty; reason for change Data Entry Error	(b) (4) Megan Loughran (b) (4)	03 Nov 2020 19:06:11
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:07:14
User entered '28 Aug 2020'	Megan Loughran (b) (4)	01 Sep 2020 06:42:12

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:07:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Yes (Y)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:05:07
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:07:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered empty.	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:05:07
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:07:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered empty.	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:05:07
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 00:05:07

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.	(b) (4)	23 Oct 2020 22:07:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '28 Aug 2020'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:05:07
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:07:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered '16:47'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:05:07
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '28 Aug 2020 16:47'	System	29 Aug 2020 00:05:07

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:07:38
User signature succeeded.	Stephen Spector (b) (4)	31 Aug 2020 23:45:19
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Fanny Delebecque (b) (4)	29 Aug 2020 00:05:07
	(b) (4)	

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		23 Oct 2020 22:07:38
User entered 'ONCE'	System	29 Aug 2020 00:05:07

US3642035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 00:05:07

US3642035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:47
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:29

US3642035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:47
User entered '28 Aug 2020'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:29

US3642035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:47
User entered '15:50'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:29

US3642035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '28 Aug 2020 15:50'	System	01 Sep 2020 06:42:29

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:54
User entered '28 Aug 2020'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Megan Loughran (b) (4)	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:54
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:54
User entered '16:00'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '28 Aug 2020 16:00'	System	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Megan Loughran (b) (4)	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:54
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:07:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered empty.	System	01 Sep 2020 06:42:47

US3642035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:08:00
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:42:51

US3642035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	01 Sep 2020 06:42:51

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:12:49', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6f8732c6-d6a4-42df-9765-fa7299d9048f' User entered 'Yes (Y)'	System	29 Aug 2020 00:13:15
	System	29 Aug 2020 00:13:15

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:12:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6f8732c6-d6a4-42df-9765-fa7299d9048f' User entered '97.9'	System	29 Aug 2020 00:13:15
	System	29 Aug 2020 00:13:15

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:13:02', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6f8732c6-d6a4-42df-9765-fa7299d9048f' User entered 'No (N)'	System	29 Aug 2020 00:13:15
	System	29 Aug 2020 00:13:15

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:13:10', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6f8732c6-d6a4-42df-9765-fa7299d9048f' User entered '28 Aug 2020 17:13'	System	29 Aug 2020 00:13:15
	System	29 Aug 2020 00:13:15

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 17:07'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 19:37'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:52:54', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd1d1dcd3-39ad-49c0-855c-918b766d386a' User entered 'Yes (Y)'	System	29 Aug 2020 04:54:17
	System	29 Aug 2020 04:54:17

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:53:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd1d1dcd3-39ad-49c0-855c-918b766d386a' User entered '97.1'	System	29 Aug 2020 04:54:17
	System	29 Aug 2020 04:54:17

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:06', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd1d1dcd3-39ad-49c0-855c-918b766d386a' User entered 'No (N)'	System	29 Aug 2020 04:54:17
	System	29 Aug 2020 04:54:17

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:14', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd1d1dcd3-39ad-49c0-855c-918b766d386a' User entered '28 Aug 2020 21:54'	System	29 Aug 2020 04:54:17
	System	29 Aug 2020 04:54:17

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 20:32'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 2'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:41:17', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4941e1f-882d-404b-b768-88f86a2f2231' User entered 'Yes (Y)'	System	29 Aug 2020 19:43:12
	System	29 Aug 2020 19:43:12

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:42:52', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4941e1f-882d-404b-b768-88f86a2f2231' User entered '97.3'	System	29 Aug 2020 19:43:12
	System	29 Aug 2020 19:43:12

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:42:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4941e1f-882d-404b-b768-88f86a2f2231' User entered 'No (N)'	System	29 Aug 2020 19:43:12
	System	29 Aug 2020 19:43:12

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:10', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4941e1f-882d-404b-b768-88f86a2f2231' User entered '29 Aug 2020 12:43'	System	29 Aug 2020 19:43:12
	System	29 Aug 2020 19:43:12

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 3'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:43:06', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a3fb6d4d-b32e-441f-8753-b7004720597a' User entered 'Yes (Y)'	System	31 Aug 2020 00:43:26
	System	31 Aug 2020 00:43:26

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:43:12', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a3fb6d4d-b32e-441f-8753-b7004720597a' User entered '98.1'	System	31 Aug 2020 00:43:26
	System	31 Aug 2020 00:43:26

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:43:19', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a3fb6d4d-b32e-441f-8753-b7004720597a' User entered 'No (N)'	System	31 Aug 2020 00:43:26
	System	31 Aug 2020 00:43:26

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:43:24', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a3fb6d4d-b32e-441f-8753-b7004720597a' User entered '30 Aug 2020 17:43'	System	31 Aug 2020 00:43:26
	System	31 Aug 2020 00:43:26

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 4'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:30:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '593d03c8-e1f3-4537-824f-ffbcac9f04e0' User entered 'Yes (Y)'	System	01 Sep 2020 15:31:42
	System	01 Sep 2020 15:31:42

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:10', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '593d03c8-e1f3-4537-824f-ffbcac9f04e0' User entered '98.8'	System	01 Sep 2020 15:31:42
	System	01 Sep 2020 15:31:42

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:23', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '593d03c8-e1f3-4537-824f-ffbcac9f04e0'	System	01 Sep 2020 15:31:42
User entered 'Yes (Y)'	System	01 Sep 2020 15:31:42

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT CONTACTED BY STUDY STAFF. SEE SAFETY CALL SOURCE DOC FOR ADDITIONAL INFORMATION. ' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 04:16:49
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT CONTACTED BY STUDY STAFF. SEE SAFETY CALL SOURCE DOC FOR ADDITIONAL INFORMATION. ' (Site from System).	Colleen McLellan (b) (4) (b) (4)	19 Nov 2020 22:04:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Sep 2020 15:31:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:30', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '593d03c8-e1f3-4537-824f-ffbcac9f04e0'	System	01 Sep 2020 15:31:42
User entered '1'	System	01 Sep 2020 15:31:42

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:30', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '593d03c8-e1f3-4537-824f-ffbcac9f04e0'	System	01 Sep 2020 15:31:42
User entered '0'	System	01 Sep 2020 15:31:42

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:37', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '593d03c8-e1f3-4537-824f-ffbcac9f04e0' User entered '01 Sep 2020 08:31'	System	01 Sep 2020 15:31:42
	System	01 Sep 2020 15:31:42

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 5'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:49:29', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f629b3c7-5df0-4c27-aef6-71451434b452'	System	02 Sep 2020 04:49:57
User entered 'Yes (Y)'	System	02 Sep 2020 04:49:57

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:49:35', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f629b3c7-5df0-4c27-aef6-71451434b452' User entered '98.7'	System	02 Sep 2020 04:49:57
	System	02 Sep 2020 04:49:57

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:49:41', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f629b3c7-5df0-4c27-aef6-71451434b452'	System	02 Sep 2020 04:49:57
User entered 'Yes (Y)'	System	02 Sep 2020 04:49:57

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT CONTACTED BY STUDY STAFF. SEE SAFETY CALL SOURCE DOC FOR ADDITIONAL INFORMATION. ' (Site from System).	Colleen McLellan (b) (4)	20 Nov 2020 04:16:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Nov 2020 22:04:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:49:45', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f629b3c7-5df0-4c27-aef6-71451434b452'	System	(b) (4)
User entered '1'	System	02 Sep 2020 04:49:57
	System	02 Sep 2020 04:49:57
	System	02 Sep 2020 04:49:57

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:49:45', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f629b3c7-5df0-4c27-aef6-71451434b452' User entered '0'	System	02 Sep 2020 04:49:57
	System	02 Sep 2020 04:49:57

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:49:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f629b3c7-5df0-4c27-aef6-71451434b452'	System	02 Sep 2020 04:49:57
User entered '01 Sep 2020 21:49'	System	02 Sep 2020 04:49:57

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 6'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:25:37', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '841374b1-6e9b-4c40-8658-60ae232b0304' User entered 'Yes (Y)'	System	03 Sep 2020 03:26:07
	System	03 Sep 2020 03:26:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:25:43', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '841374b1-6e9b-4c40-8658-60ae232b0304' User entered '99.1'	System	03 Sep 2020 03:26:07
	System	03 Sep 2020 03:26:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '841374b1-6e9b-4c40-8658-60ae232b0304'	System	03 Sep 2020 03:26:07
User entered 'No (N)'	System	03 Sep 2020 03:26:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:05', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '841374b1-6e9b-4c40-8658-60ae232b0304' User entered '02 Sep 2020 20:26'	System	03 Sep 2020 03:26:07
	System	03 Sep 2020 03:26:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 7'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:13:19', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '245f6d7f-dfad-4921-b9d8-f5b8f20d968a' User entered 'None (1)'	System	29 Aug 2020 00:13:55
	System	29 Aug 2020 00:13:55

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:13:29', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '245f6d7f-dfad-4921-b9d8-f5b8f20d968a' User entered 'No (N)'	System	29 Aug 2020 00:13:55
	System	29 Aug 2020 00:13:55

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:13:36', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '245f6d7f-dfad-4921-b9d8-f5b8f20d968a' User entered 'No (N)'	System	29 Aug 2020 00:13:55
	System	29 Aug 2020 00:13:55

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:13:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '245f6d7f-dfad-4921-b9d8-f5b8f20d968a' User entered 'None (1)'	System	29 Aug 2020 00:13:55
	System	29 Aug 2020 00:13:55

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:13:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '245f6d7f-dfad-4921-b9d8-f5b8f20d968a' User entered '28 Aug 2020 17:13'	System	29 Aug 2020 00:13:55
	System	29 Aug 2020 00:13:55

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 17:07'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 19:37'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:22', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6277a50b-fff8-402b-8896-35ac7c0e9660'	System	29 Aug 2020 04:54:37
User entered 'None (1)'	System	29 Aug 2020 04:54:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:25', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6277a50b-fff8-402b-8896-35ac7c0e9660' User entered 'No (N)'	System	29 Aug 2020 04:54:37
	System	29 Aug 2020 04:54:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:28', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6277a50b-fff8-402b-8896-35ac7c0e9660' User entered 'No (N)'	System	29 Aug 2020 04:54:37
	System	29 Aug 2020 04:54:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:30', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6277a50b-fff8-402b-8896-35ac7c0e9660'	System	29 Aug 2020 04:54:37
User entered 'None (1)'	System	29 Aug 2020 04:54:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:34', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6277a50b-fff8-402b-8896-35ac7c0e9660' User entered '28 Aug 2020 21:54'	System	29 Aug 2020 04:54:37
	System	29 Aug 2020 04:54:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 20:32'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 2'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:18', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '19b026b7-a04d-492c-a22b-c66243cde37f' User entered 'None (1)'	System	29 Aug 2020 19:43:37
	System	29 Aug 2020 19:43:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:22', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '19b026b7-a04d-492c-a22b-c66243cde37f' User entered 'No (N)'	System	29 Aug 2020 19:43:37
	System	29 Aug 2020 19:43:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:26', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '19b026b7-a04d-492c-a22b-c66243cde37f' User entered 'No (N)'	System	29 Aug 2020 19:43:37
	System	29 Aug 2020 19:43:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:29', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '19b026b7-a04d-492c-a22b-c66243cde37f' User entered 'None (1)'	System	29 Aug 2020 19:43:37
	System	29 Aug 2020 19:43:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:35', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '19b026b7-a04d-492c-a22b-c66243cde37f' User entered '29 Aug 2020 12:43'	System	29 Aug 2020 19:43:37
	System	29 Aug 2020 19:43:37

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 3'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:36', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6275267b-7f88-4a28-b9bc-100083fc6461' User entered 'None (1)'	System	31 Aug 2020 00:43:04
	System	31 Aug 2020 00:43:04

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:40', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6275267b-7f88-4a28-b9bc-100083fc6461' User entered 'No (N)'	System	31 Aug 2020 00:43:04
	System	31 Aug 2020 00:43:04

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:50', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6275267b-7f88-4a28-b9bc-100083fc6461' User entered 'No (N)'	System	31 Aug 2020 00:43:04
	System	31 Aug 2020 00:43:04

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6275267b-7f88-4a28-b9bc-100083fc6461' User entered 'None (1)'	System	31 Aug 2020 00:43:04
	System	31 Aug 2020 00:43:04

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:59', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6275267b-7f88-4a28-b9bc-100083fc6461' User entered '30 Aug 2020 17:42'	System	31 Aug 2020 00:43:04
	System	31 Aug 2020 00:43:04

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 4'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:46', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3e8de5af-db68-4738-bf1b-b15adae5ab49'	System	01 Sep 2020 15:31:59
User entered 'None (1)'	System	01 Sep 2020 15:31:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:49', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3e8de5af-db68-4738-bf1b-b15adae5ab49' User entered 'No (N)'	System	01 Sep 2020 15:31:59
	System	01 Sep 2020 15:31:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:52', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3e8de5af-db68-4738-bf1b-b15adae5ab49' User entered 'No (N)'	System	01 Sep 2020 15:31:59
	System	01 Sep 2020 15:31:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:55', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3e8de5af-db68-4738-bf1b-b15adae5ab49' User entered 'None (1)'	System	01 Sep 2020 15:31:59
	System	01 Sep 2020 15:31:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:31:58', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3e8de5af-db68-4738-bf1b-b15adae5ab49' User entered '01 Sep 2020 08:31'	System	01 Sep 2020 15:31:59
	System	01 Sep 2020 15:31:59

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 5'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:49:58', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'fd10b4d5-f275-470d-9bfb-2933fbeb0480'	System	02 Sep 2020 04:50:14
User entered 'None (1)'	System	02 Sep 2020 04:50:14

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:02', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'fd10b4d5-f275-470d-9bfb-2933fbeb0480' User entered 'No (N)'	System	02 Sep 2020 04:50:14
	System	02 Sep 2020 04:50:14

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:05', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'fd10b4d5-f275-470d-9bfb-2933fbeb0480' User entered 'No (N)'	System	02 Sep 2020 04:50:14
	System	02 Sep 2020 04:50:14

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:07', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'fd10b4d5-f275-470d-9bfb-2933fbeb0480'	System	02 Sep 2020 04:50:14
User entered 'None (1)'	System	02 Sep 2020 04:50:14

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:12', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'fd10b4d5-f275-470d-9bfb-2933fbeb0480'	System	02 Sep 2020 04:50:14
User entered '01 Sep 2020 21:50'	System	02 Sep 2020 04:50:14

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 6'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:16', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f3b35cb4-640c-4f0e-b768-8f9ff328e77c' User entered 'None (1)'	System	03 Sep 2020 03:26:30
	System	03 Sep 2020 03:26:30

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:20', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f3b35cb4-640c-4f0e-b768-8f9ff328e77c' User entered 'No (N)'	System	03 Sep 2020 03:26:30
	System	03 Sep 2020 03:26:30

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:24', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f3b35cb4-640c-4f0e-b768-8f9ff328e77c'	System	03 Sep 2020 03:26:30
User entered 'No (N)'	System	03 Sep 2020 03:26:30

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:26', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f3b35cb4-640c-4f0e-b768-8f9ff328e77c' User entered 'None (1)'	System	03 Sep 2020 03:26:30
	System	03 Sep 2020 03:26:30

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:29', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f3b35cb4-640c-4f0e-b768-8f9ff328e77c'	System	03 Sep 2020 03:26:30
User entered '02 Sep 2020 20:26'	System	03 Sep 2020 03:26:30

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 7'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67' User entered 'None (0)'	System	29 Aug 2020 00:14:41
	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:03', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67'	System	29 Aug 2020 00:14:41
User entered 'None (0)'	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:05', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67' User entered 'None (0)'	System	29 Aug 2020 00:14:41
	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:11', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67'	System	29 Aug 2020 00:14:41
User entered 'None (0)'	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:13', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67' User entered 'None (0)'	System	29 Aug 2020 00:14:41
	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:15', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67'	System	29 Aug 2020 00:14:41
User entered 'None (0)'	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:35', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67'	System	29 Aug 2020 00:14:41
User entered 'No (N)'	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T17:14:38', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4f1062a4-5c6b-4d43-b46c-ab49a4f89f67'	System	29 Aug 2020 00:14:41
User entered '28 Aug 2020 17:14'	System	29 Aug 2020 00:14:41

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 17:07'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 19:37'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:49', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered 'None (0)'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:51', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered 'None (0)'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered 'None (0)'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:55', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered 'None (0)'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered 'None (0)'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:54:59', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered 'None (0)'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:55:03', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered 'No (N)'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-28T21:55:07', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f2516bad-ec93-4927-a1ea-06a1a8dec2a1' User entered '28 Aug 2020 21:55'	System	29 Aug 2020 04:55:11
	System	29 Aug 2020 04:55:11

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Aug 2020 20:32'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 2'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:41', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered 'None (0)'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:43', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered 'None (0)'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:47', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered 'None (0)'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:49', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered 'None (0)'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:51', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered 'None (0)'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered 'None (0)'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:43:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered 'No (N)'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-29T12:44:02', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '9b7f9e1e-e50e-43a4-a946-9281ad60579a' User entered '29 Aug 2020 12:44'	System	29 Aug 2020 19:44:04
	System	29 Aug 2020 19:44:04

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 3'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:09', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered 'None (0)'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:12', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered 'None (0)'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:14', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered 'None (0)'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:17', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered 'None (0)'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:19', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered 'None (0)'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:21', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered 'None (0)'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:24', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered 'No (N)'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-08-30T17:42:32', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5c2f35d1-8837-43d8-adf4-b2b38da6ef14' User entered '30 Aug 2020 17:42'	System	31 Aug 2020 00:42:34
	System	31 Aug 2020 00:42:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 4'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:04', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c' User entered 'None (0)'	System	01 Sep 2020 15:32:54
	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:06', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c' User entered 'None (0)'	System	01 Sep 2020 15:32:54
	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:10', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c' User entered 'None (0)'	System	01 Sep 2020 15:32:54
	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:13', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c' User entered 'None (0)'	System	01 Sep 2020 15:32:54
	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:34', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c'	System	01 Sep 2020 15:32:54
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:41', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c'	System	01 Sep 2020 15:32:54
User entered 'Some interference with activity not requiring medical attention (2)'	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:46', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c' User entered 'Yes (Y)'	System	01 Sep 2020 15:32:54
	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T08:32:51', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '6502513d-d99a-430f-b563-693df0fca59c' User entered '01 Sep 2020 08:32'	System	01 Sep 2020 15:32:54
	System	01 Sep 2020 15:32:54

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 5'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:18', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248' User entered 'None (0)'	System	02 Sep 2020 04:50:59
	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:19', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248' User entered 'None (0)'	System	02 Sep 2020 04:50:59
	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:22', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248' User entered 'None (0)'	System	02 Sep 2020 04:50:59
	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:24', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248' User entered 'None (0)'	System	02 Sep 2020 04:50:59
	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:39', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248' User entered 'None (0)'	System	02 Sep 2020 04:50:59
	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:41', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248' User entered 'None (0)'	System	02 Sep 2020 04:50:59
	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:47', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248' User entered 'Yes (Y)'	System	02 Sep 2020 04:50:59
	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-01T21:50:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e4533f81-7986-4657-b3ad-9e2259967248'	System	02 Sep 2020 04:50:59
User entered '01 Sep 2020 21:50'	System	02 Sep 2020 04:50:59

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 6'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:35', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered 'None (0)'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:36', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered 'None (0)'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:38', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered 'None (0)'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:41', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered 'None (0)'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:43', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered 'None (0)'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:45', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered 'None (0)'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:51', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered 'No (N)'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279F549A-584E-47E8-97C5-81F7428C8E35)', Time: '2020-09-02T20:26:54', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'db30bca0-715f-4de2-9b88-b8a750f6713a' User entered '02 Sep 2020 20:26'	System	03 Sep 2020 03:26:56
	System	03 Sep 2020 03:26:56

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 7'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 00:05:07

US3642035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:04:20
User entered 'Yes (Y)'	Nancy Tang (b) (4)	06 Sep 2020 03:27:30

US3642035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:04:20
User entered '05 Sep 2020'	Nancy Tang (b) (4)	06 Sep 2020 03:27:30

US3642035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:04:20
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	06 Sep 2020 03:27:30

US3642035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:04:20
User entered empty.	Nancy Tang (b) (4)	06 Sep 2020 03:27:30

US3642035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:04:24
User entered 'Yes (Y)'	Nancy Tang (b) (4)	06 Sep 2020 03:27:37

US3642035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	06 Sep 2020 03:27:37

US3642035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:05:27
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:12:05

US3642035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:05:27
User entered '14 Sep 2020'	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:12:05

US3642035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:05:27
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:12:05

US3642035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:05:27
User entered empty.	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:12:05

US3642035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:05:31
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	14 Sep 2020 23:12:09

US3642035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	14 Sep 2020 23:12:09

US3642035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:07:10
User entered 'Yes (Y)'		19 Sep 2020 17:17:55

US3642035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:07:10
User entered '19 Sep 2020'		19 Sep 2020 17:17:55

US3642035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:07:10
User entered 'Contact Made (CONTACT MADE)'		19 Sep 2020 17:17:55

US3642035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:07:10
User entered empty.		19 Sep 2020 17:17:55

US3642035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:07:14
User entered 'Yes (Y)'		19 Sep 2020 17:18:00

US3642035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	19 Sep 2020 17:18:00

US3642035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:07:44
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 22:55:24

US3642035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:07:44
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 22:55:24

US3642035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:07:44
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 22:55:24

US3642035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'VISIT2'	System	25 Sep 2020 22:55:24

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:15
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:17
User entered '25 Sep 2020'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:19
User entered '15:09'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '25 Sep 2020 15:09'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:21
User entered '97.7' F	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User closed query 'Per source axillary is not indicated. Please reconcile.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:38:11
		23 Nov 2020 21:38:09
Query 'Per source axillary is not indicated. Please reconcile.' answered with 'data entry error - temp taken orally ' (Site from CRA).	Colleen McLellan (b) (4)	19 Nov 2020 22:04:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	19 Nov 2020 22:03:49
User opened query 'Per source axillary is not indicated. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:10:08
User entered 'Axillary (Axillary)'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:24
User entered empty.	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:26
User entered '64'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'bpm'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:27
User entered '16'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'breaths/min'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:29
User entered '133'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:30
User entered '76'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:57
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:10:59
User entered '25 Sep 2020'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:00
User entered '17:10'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '25 Sep 2020 17:10'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:02
User entered '98.3' F	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User closed query 'Per source axillary is not indicated. Please reconcile.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:38:17
		23 Nov 2020 21:38:16
Query 'Per source axillary is not indicated. Please reconcile.' answered with 'data entry error - temp taken orally ' (Site from CRA).	Colleen McLellan (b) (4)	19 Nov 2020 22:04:28
User entered 'Oral (Oral)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	19 Nov 2020 22:03:49
User opened query 'Per source axillary is not indicated. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:10:54
User entered 'Axillary (Axillary)'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:04
User entered empty.	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:10
User entered '66'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'bpm'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:12
User entered '15'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'breaths/min'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:13
User entered '122'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:15
User entered '70'	Son Do (b) (4)	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	28 Sep 2020 17:36:11

US3642035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:29
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 17:36:20

US3642035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:29
User entered '25 Sep 2020'	Son Do (b) (4)	28 Sep 2020 17:36:20

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:54
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:54
User entered empty.	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:54
User entered '25 Sep 2020'	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:54
User entered '16:40'	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '25 Sep 2020 16:40'	System	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:11:54
User entered 'Right Arm (RIGHT ARM)'	Megan Loughran (b) (4) (b) (4)	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
DataPoint Verified.		06 Nov 2020 20:11:54
User entered 'ONCE'	System	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 23:44:17

US3642035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:05
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 17:36:32

US3642035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:05
User entered '25 Sep 2020'	Son Do (b) (4)	28 Sep 2020 17:36:32

US3642035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:05
User entered '16:00'	Son Do (b) (4)	28 Sep 2020 17:36:32

US3642035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '25 Sep 2020 16:00'	System	28 Sep 2020 17:36:32

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:12
User entered '25 Sep 2020'	Son Do (b) (4)	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:12
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:12
User entered '16:03'	Son Do (b) (4)	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:11:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '25 Sep 2020 16:03'	System	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:12
User entered 'No (N)'	Son Do (b) (4)	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:12
User entered empty.	Son Do (b) (4)	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:11:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered empty.	System	28 Sep 2020 17:36:44

US3642035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:12:17
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 17:36:56

US3642035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	28 Sep 2020 17:36:56

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:14', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8fa45fe7-2089-40fc-b280-2f8694bd262b' User entered 'Yes (Y)'	System	26 Sep 2020 00:03:38
	System	26 Sep 2020 00:03:38

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:22', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8fa45fe7-2089-40fc-b280-2f8694bd262b' User entered '98.3'	System	26 Sep 2020 00:03:38
	System	26 Sep 2020 00:03:38

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:27', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8fa45fe7-2089-40fc-b280-2f8694bd262b' User entered 'No (N)'	System	26 Sep 2020 00:03:38
	System	26 Sep 2020 00:03:38

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:32', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8fa45fe7-2089-40fc-b280-2f8694bd262b' User entered '25 Sep 2020 17:03'	System	26 Sep 2020 00:03:38
	System	26 Sep 2020 00:03:38

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 17:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 19:30'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:27:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b49b6722-99ec-470b-9d88-3a76e9d1fc86' User entered 'Yes (Y)'	System	26 Sep 2020 03:28:20
	System	26 Sep 2020 03:28:20

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:28:04', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b49b6722-99ec-470b-9d88-3a76e9d1fc86' User entered '98.3'	System	26 Sep 2020 03:28:20
	System	26 Sep 2020 03:28:20

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:28:10', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b49b6722-99ec-470b-9d88-3a76e9d1fc86'	System	26 Sep 2020 03:28:20
User entered 'No (N)'	System	26 Sep 2020 03:28:20

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:28:17', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b49b6722-99ec-470b-9d88-3a76e9d1fc86' User entered '25 Sep 2020 20:28'	System	26 Sep 2020 03:28:20
	System	26 Sep 2020 03:28:20

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 20:25'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 2'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:46:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b0d68946-ecd2-4557-a026-3be217d70873'	System	27 Sep 2020 03:47:36
User entered 'Yes (Y)'	System	27 Sep 2020 03:47:36

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:46:55', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b0d68946-ecd2-4557-a026-3be217d70873' User entered '97.5'	System	27 Sep 2020 03:47:36
	System	27 Sep 2020 03:47:36

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b0d68946-ecd2-4557-a026-3be217d70873'	System	27 Sep 2020 03:47:36
User entered 'No (N)'	System	27 Sep 2020 03:47:36

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:04', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'b0d68946-ecd2-4557-a026-3be217d70873'	System	27 Sep 2020 03:47:36
User entered '26 Sep 2020 20:47'	System	27 Sep 2020 03:47:36

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 3'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:49:39', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e3e20878-527e-4446-9e3c-b01906071e09' User entered 'Yes (Y)'	System	28 Sep 2020 02:49:54
	System	28 Sep 2020 02:49:54

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:49:44', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e3e20878-527e-4446-9e3c-b01906071e09' User entered '98.0'	System	28 Sep 2020 02:49:54
	System	28 Sep 2020 02:49:54

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:49:47', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e3e20878-527e-4446-9e3c-b01906071e09' User entered 'No (N)'	System	28 Sep 2020 02:49:54
	System	28 Sep 2020 02:49:54

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:49:52', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e3e20878-527e-4446-9e3c-b01906071e09' User entered '27 Sep 2020 19:49'	System	28 Sep 2020 02:49:54
	System	28 Sep 2020 02:49:54

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 4'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:01:11', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '64d41126-e215-445d-bcf4-6643c603a87a' User entered 'Yes (Y)'	System	29 Sep 2020 04:01:58
	System	29 Sep 2020 04:01:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:01:49', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '64d41126-e215-445d-bcf4-6643c603a87a' User entered '97.7'	System	29 Sep 2020 04:01:58
	System	29 Sep 2020 04:01:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:01:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '64d41126-e215-445d-bcf4-6643c603a87a' User entered 'No (N)'	System	29 Sep 2020 04:01:58
	System	29 Sep 2020 04:01:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:01:55', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '64d41126-e215-445d-bcf4-6643c603a87a' User entered '28 Sep 2020 21:01'	System	29 Sep 2020 04:01:58
	System	29 Sep 2020 04:01:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 5'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:39:42', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bdd8ff2d-0905-499b-a185-2e096aa3b121' User entered 'Yes (Y)'	System	30 Sep 2020 03:39:58
	System	30 Sep 2020 03:39:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:39:47', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bdd8ff2d-0905-499b-a185-2e096aa3b121' User entered '98.2'	System	30 Sep 2020 03:39:58
	System	30 Sep 2020 03:39:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:39:50', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bdd8ff2d-0905-499b-a185-2e096aa3b121' User entered 'No (N)'	System	30 Sep 2020 03:39:58
	System	30 Sep 2020 03:39:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:39:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bdd8ff2d-0905-499b-a185-2e096aa3b121' User entered '29 Sep 2020 20:39'	System	30 Sep 2020 03:39:58
	System	30 Sep 2020 03:39:58

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 6'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:19', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'cc433ceb-e080-4f76-b6d3-5a5d508bac0c' User entered 'Yes (Y)'	System	01 Oct 2020 16:35:37
	System	01 Oct 2020 16:35:37

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:24', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'cc433ceb-e080-4f76-b6d3-5a5d508bac0c' User entered '98.2'	System	01 Oct 2020 16:35:37
	System	01 Oct 2020 16:35:37

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:27', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'cc433ceb-e080-4f76-b6d3-5a5d508bac0c' User entered 'No (N)'	System	01 Oct 2020 16:35:37
	System	01 Oct 2020 16:35:37

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:32', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'cc433ceb-e080-4f76-b6d3-5a5d508bac0c' User entered '01 Oct 2020 09:35'	System	01 Oct 2020 16:35:37
	System	01 Oct 2020 16:35:37

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 7'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:18', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '15a849bc-eaae-483f-9f05-7b57b5c32f16' User entered 'Yes (Y)'	System	02 Oct 2020 03:17:39
	System	02 Oct 2020 03:17:39

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:25', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '15a849bc-eaae-483f-9f05-7b57b5c32f16' User entered '98.0'	System	02 Oct 2020 03:17:39
	System	02 Oct 2020 03:17:39

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:32', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '15a849bc-eaae-483f-9f05-7b57b5c32f16'	System	02 Oct 2020 03:17:39
User entered 'No (N)'	System	02 Oct 2020 03:17:39

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:38', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '15a849bc-eaae-483f-9f05-7b57b5c32f16' User entered '01 Oct 2020 20:17'	System	02 Oct 2020 03:17:39
	System	02 Oct 2020 03:17:39

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '0b66d705-0b39-4238-87bf-7357fa1d945d' User entered 'None (1)'	System	26 Sep 2020 00:04:04
	System	26 Sep 2020 00:04:04

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:51', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '0b66d705-0b39-4238-87bf-7357fa1d945d' User entered 'No (N)'	System	26 Sep 2020 00:04:04
	System	26 Sep 2020 00:04:04

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:54', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '0b66d705-0b39-4238-87bf-7357fa1d945d' User entered 'No (N)'	System	26 Sep 2020 00:04:04
	System	26 Sep 2020 00:04:04

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '0b66d705-0b39-4238-87bf-7357fa1d945d' User entered 'None (1)'	System	26 Sep 2020 00:04:04
	System	26 Sep 2020 00:04:04

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:03:59', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '0b66d705-0b39-4238-87bf-7357fa1d945d' User entered '25 Sep 2020 17:03'	System	26 Sep 2020 00:04:04
	System	26 Sep 2020 00:04:04

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 17:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 19:30'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:28:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '730f542c-bb60-4a3f-88fc-591214d284d3' User entered 'None (1)'	System	26 Sep 2020 03:29:17
	System	26 Sep 2020 03:29:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:28:59', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '730f542c-bb60-4a3f-88fc-591214d284d3' User entered 'No (N)'	System	26 Sep 2020 03:29:17
	System	26 Sep 2020 03:29:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:03', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '730f542c-bb60-4a3f-88fc-591214d284d3' User entered 'No (N)'	System	26 Sep 2020 03:29:17
	System	26 Sep 2020 03:29:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:10', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '730f542c-bb60-4a3f-88fc-591214d284d3' User entered 'None (1)'	System	26 Sep 2020 03:29:17
	System	26 Sep 2020 03:29:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:13', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '730f542c-bb60-4a3f-88fc-591214d284d3' User entered '25 Sep 2020 20:29'	System	26 Sep 2020 03:29:17
	System	26 Sep 2020 03:29:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 20:25'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 2'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:13', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e9bc9361-5432-4429-a6eb-381f0814c913'	System	27 Sep 2020 03:47:40
User entered 'None (1)'	System	27 Sep 2020 03:47:40

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:17', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e9bc9361-5432-4429-a6eb-381f0814c913'	System	27 Sep 2020 03:47:40
User entered 'No (N)'	System	27 Sep 2020 03:47:40

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:20', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e9bc9361-5432-4429-a6eb-381f0814c913'	System	27 Sep 2020 03:47:40
User entered 'No (N)'	System	27 Sep 2020 03:47:40

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:23', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e9bc9361-5432-4429-a6eb-381f0814c913'	System	27 Sep 2020 03:47:40
User entered 'None (1)'	System	27 Sep 2020 03:47:40

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:33', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'e9bc9361-5432-4429-a6eb-381f0814c913'	System	27 Sep 2020 03:47:40
User entered '26 Sep 2020 20:47'	System	27 Sep 2020 03:47:40

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 3'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:01', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ef43d06-ea2f-4f45-bf07-de9855a55a35'	System	28 Sep 2020 02:50:17
User entered 'None (1)'	System	28 Sep 2020 02:50:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:04', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ef43d06-ea2f-4f45-bf07-de9855a55a35'	System	28 Sep 2020 02:50:17
User entered 'No (N)'	System	28 Sep 2020 02:50:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:08', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ef43d06-ea2f-4f45-bf07-de9855a55a35'	System	28 Sep 2020 02:50:17
User entered 'No (N)'	System	28 Sep 2020 02:50:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:12', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ef43d06-ea2f-4f45-bf07-de9855a55a35'	System	28 Sep 2020 02:50:17
User entered 'None (1)'	System	28 Sep 2020 02:50:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:16', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ef43d06-ea2f-4f45-bf07-de9855a55a35'	System	28 Sep 2020 02:50:17
User entered '27 Sep 2020 19:50'	System	28 Sep 2020 02:50:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 4'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:36', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eb694748-7087-4d9c-b719-074de04e12c3'	System	29 Sep 2020 04:00:53
User entered 'None (1)'	System	29 Sep 2020 04:00:53

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:39', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eb694748-7087-4d9c-b719-074de04e12c3'	System	29 Sep 2020 04:00:53
User entered 'No (N)'	System	29 Sep 2020 04:00:53

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:42', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eb694748-7087-4d9c-b719-074de04e12c3'	System	29 Sep 2020 04:00:53
User entered 'No (N)'	System	29 Sep 2020 04:00:53

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:44', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eb694748-7087-4d9c-b719-074de04e12c3'	System	29 Sep 2020 04:00:53
User entered 'None (1)'	System	29 Sep 2020 04:00:53

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:47', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eb694748-7087-4d9c-b719-074de04e12c3' User entered '28 Sep 2020 21:00'	System	29 Sep 2020 04:00:53
	System	29 Sep 2020 04:00:53

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 5'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bcc0b39b-1645-49ec-99c4-299817265cd1' User entered 'None (1)'	System	30 Sep 2020 03:40:14
	System	30 Sep 2020 03:40:14

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:02', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bcc0b39b-1645-49ec-99c4-299817265cd1' User entered 'No (N)'	System	30 Sep 2020 03:40:14
	System	30 Sep 2020 03:40:14

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:05', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bcc0b39b-1645-49ec-99c4-299817265cd1' User entered 'No (N)'	System	30 Sep 2020 03:40:14
	System	30 Sep 2020 03:40:14

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:07', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bcc0b39b-1645-49ec-99c4-299817265cd1' User entered 'None (1)'	System	30 Sep 2020 03:40:14
	System	30 Sep 2020 03:40:14

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:09', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'bcc0b39b-1645-49ec-99c4-299817265cd1' User entered '29 Sep 2020 20:40'	System	30 Sep 2020 03:40:14
	System	30 Sep 2020 03:40:14

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 6'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:37', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '80e8f674-bc2b-41eb-9a66-4db6640b6117'	System	01 Oct 2020 16:35:49
User entered 'None (1)'	System	01 Oct 2020 16:35:49

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:39', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '80e8f674-bc2b-41eb-9a66-4db6640b6117' User entered 'No (N)'	System	01 Oct 2020 16:35:49
	System	01 Oct 2020 16:35:49

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:41', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '80e8f674-bc2b-41eb-9a66-4db6640b6117' User entered 'No (N)'	System	01 Oct 2020 16:35:49
	System	01 Oct 2020 16:35:49

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:43', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '80e8f674-bc2b-41eb-9a66-4db6640b6117'	System	01 Oct 2020 16:35:49
User entered 'None (1)'	System	01 Oct 2020 16:35:49

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:46', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '80e8f674-bc2b-41eb-9a66-4db6640b6117' User entered '01 Oct 2020 09:35'	System	01 Oct 2020 16:35:49
	System	01 Oct 2020 16:35:49

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 7'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:44', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eab72626-8bc0-4f8d-a407-cdc9f148165' User entered 'None (1)'	System	02 Oct 2020 03:18:02
	System	02 Oct 2020 03:18:02

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:47', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eab72626-8bc0-4f8d-a407-cdcd9f148165' User entered 'No (N)'	System	02 Oct 2020 03:18:02
	System	02 Oct 2020 03:18:02

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:49', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eab72626-8bc0-4f8d-a407-cdcd9f148165' User entered 'No (N)'	System	02 Oct 2020 03:18:02
	System	02 Oct 2020 03:18:02

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:52', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eab72626-8bc0-4f8d-a407-cdc9f148165'	System	02 Oct 2020 03:18:02
User entered 'None (1)'	System	02 Oct 2020 03:18:02

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:17:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'eab72626-8bc0-4f8d-a407-cdcd9f148165' User entered '01 Oct 2020 20:17'	System	02 Oct 2020 03:18:02
	System	02 Oct 2020 03:18:02

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:12', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered 'None (0)'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:14', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered 'None (0)'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:16', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered 'None (0)'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:18', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered 'None (0)'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:19', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered 'None (0)'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:21', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered 'None (0)'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:24', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered 'No (N)'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T17:04:27', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '38734ae0-a9a2-49f4-8e10-e6f973065a8a' User entered '25 Sep 2020 17:04'	System	26 Sep 2020 00:04:30
	System	26 Sep 2020 00:04:30

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 17:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 19:30'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:21', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered 'None (0)'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:23', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered 'None (0)'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:25', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered 'None (0)'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:27', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered 'None (0)'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:29', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered 'None (0)'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:31', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered 'None (0)'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:34', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered 'No (N)'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-25T20:29:38', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd78eefb7-8982-4947-b436-742e8ad53a31' User entered '25 Sep 2020 20:29'	System	26 Sep 2020 03:29:39
	System	26 Sep 2020 03:29:39

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '25 Sep 2020 20:25'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 2'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered 'None (0)'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:47:59', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered 'None (0)'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:48:02', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered 'None (0)'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:48:05', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered 'None (0)'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:48:07', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered 'None (0)'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:48:09', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered 'None (0)'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:48:21', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered 'No (N)'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-26T20:48:26', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3a14b291-4b04-4bd0-bb16-355490af85e5' User entered '26 Sep 2020 20:48'	System	27 Sep 2020 03:48:32
	System	27 Sep 2020 03:48:32

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 3'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:23', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered 'None (0)'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:30', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered 'None (0)'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:32', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered 'None (0)'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:33', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered 'None (0)'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:36', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered 'None (0)'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:38', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered 'None (0)'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:41', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered 'No (N)'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-27T19:50:44', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5745edfe-0433-4604-899c-d94f7a20a4bd' User entered '27 Sep 2020 19:50'	System	28 Sep 2020 02:50:47
	System	28 Sep 2020 02:50:47

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 4'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:51', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077' User entered 'None (0)'	System	29 Sep 2020 04:01:10
	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077' User entered 'None (0)'	System	29 Sep 2020 04:01:10
	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:55', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077' User entered 'None (0)'	System	29 Sep 2020 04:01:10
	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077' User entered 'None (0)'	System	29 Sep 2020 04:01:10
	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:58', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077' User entered 'None (0)'	System	29 Sep 2020 04:01:10
	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:00:59', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077' User entered 'None (0)'	System	29 Sep 2020 04:01:10
	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:01:03', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077'	System	29 Sep 2020 04:01:10
User entered 'No (N)'	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-28T21:01:06', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '59236dbd-8b94-4260-976f-e4d9c3afe077'	System	29 Sep 2020 04:01:10
User entered '28 Sep 2020 21:01'	System	29 Sep 2020 04:01:10

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 5'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:16', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257' User entered 'None (0)'	System	30 Sep 2020 03:40:56
	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:18', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257' User entered 'None (0)'	System	30 Sep 2020 03:40:56
	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:19', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257' User entered 'None (0)'	System	30 Sep 2020 03:40:56
	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:20', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257' User entered 'None (0)'	System	30 Sep 2020 03:40:56
	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:22', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257' User entered 'None (0)'	System	30 Sep 2020 03:40:56
	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:23', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257' User entered 'None (0)'	System	30 Sep 2020 03:40:56
	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:26', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257'	System	30 Sep 2020 03:40:56
User entered 'No (N)'	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-09-29T20:40:29', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a1dc7be3-7c55-4ddd-8ac6-a394aafb3257'	System	30 Sep 2020 03:40:56
User entered '29 Sep 2020 20:40'	System	30 Sep 2020 03:40:56

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 6'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:49', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered 'None (0)'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:51', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered 'None (0)'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered 'None (0)'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:55', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered 'None (0)'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered 'None (0)'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:35:58', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered 'None (0)'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:36:01', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered 'No (N)'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T09:36:03', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f84d7baa-0159-4396-ae4a-c171355bbc8c' User entered '01 Oct 2020 09:36'	System	01 Oct 2020 16:36:11
	System	01 Oct 2020 16:36:11

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	25 Sep 2020 23:44:17
User entered 'Day 7'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:03', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4'	System	02 Oct 2020 03:18:19
User entered 'None (0)'	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:05', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4'	System	02 Oct 2020 03:18:19
User entered 'None (0)'	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:07', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4' User entered 'None (0)'	System	02 Oct 2020 03:18:19
	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:09', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4' User entered 'None (0)'	System	02 Oct 2020 03:18:19
	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:11', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4' User entered 'None (0)'	System	02 Oct 2020 03:18:19
	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:13', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4' User entered 'None (0)'	System	02 Oct 2020 03:18:19
	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:16', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4' User entered 'No (N)'	System	02 Oct 2020 03:18:19
	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-01T20:18:18', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'd8541c04-12e7-466c-a603-73c6f4fb2fc4'	System	02 Oct 2020 03:18:19
User entered '01 Oct 2020 20:18'	System	02 Oct 2020 03:18:19

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 23:44:17

US3642035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:11:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 23:44:17

US3642035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:19:15
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	03 Oct 2020 21:26:11

US3642035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:19:15
User entered '3 Oct 2020'	Colleen McLellan (b) (4) (b) (4)	03 Oct 2020 21:26:11

US3642035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:19:15
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	03 Oct 2020 21:26:11

US3642035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:19:15
User entered empty.	Colleen McLellan (b) (4) (b) (4)	03 Oct 2020 21:26:11

US3642035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:19:19
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	03 Oct 2020 21:26:16

US3642035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	03 Oct 2020 21:26:16

US3642035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:21:23
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	12 Oct 2020 23:59:51

US3642035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User closed query 'Per source contact date is documented as '10OCT20'. Please reconcile. ' (Site from CRA).		19 Feb 2021 00:05:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:05:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Query 'Per source contact date is documented as '10OCT20'. Please reconcile. ' answered with 'date confirmed and corrected on source doc ' (Site from CRA).	(b) (4) Colleen McLellan (b) (4)	19 Nov 2020 22:03:05
User opened query 'Per source contact date is documented as '10OCT20'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:22:04
User entered '12 Oct 2020'	Colleen McLellan (b) (4)	12 Oct 2020 23:59:51

US3642035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:21:25
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4) (b) (4)	12 Oct 2020 23:59:51

US3642035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:21:27
User entered empty.	Colleen McLellan (b) (4) (b) (4)	12 Oct 2020 23:59:51

US3642035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:09
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	12 Oct 2020 23:59:55

US3642035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	12 Oct 2020 23:59:55

US3642035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:36
User entered 'Yes (Y)'	Nancy Tang (b) (4)	19 Oct 2020 23:33:45

US3642035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:36
User entered '19 Oct 2020'	Nancy Tang (b) (4)	19 Oct 2020 23:33:45

US3642035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:36
User entered 'Contact Made (CONTACT MADE)'	Nancy Tang (b) (4)	19 Oct 2020 23:33:45

US3642035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:22:36
User entered empty.	Nancy Tang (b) (4)	19 Oct 2020 23:33:45

US3642035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:24:07
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	19 Oct 2020 19:37:57

US3642035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	19 Oct 2020 19:37:57

US3642035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:12
User entered 'Yes (Y)'	Son Do (b) (4)	28 Oct 2020 15:14:18

US3642035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:12
User entered '26 Oct 2020'	Son Do (b) (4)	28 Oct 2020 15:14:18

US3642035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:12
User entered 'Clinic (Clinic)'	Son Do (b) (4)	28 Oct 2020 15:14:18

US3642035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'VISIT3'	System	28 Oct 2020 15:14:18

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered 'Yes (Y)'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered '26 Oct 2020'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered '13:54'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '26 Oct 2020 13:54'	System	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered '98.4' F	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered 'Oral (Oral)'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered empty.	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered '68'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'bpm'	System	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered '16'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'breaths/min'	System	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:30
User entered '98'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
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)	09 Nov 2020 03:28:16
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:26:30
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 'not clinically significant' (Site from System).	Colleen McLellan (b) (4) (b) (4)	05 Nov 2020 21:02:05
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).		28 Oct 2020 15:14:39
User entered '45'	Son Do (b) (4)	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'mmHg'	System	28 Oct 2020 15:14:39

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47

US3642035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47

US3642035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:44
User entered 'Yes (Y)'	Son Do (b) (4)	28 Oct 2020 15:15:04

US3642035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:44
User entered '26 Oct 2020'	Son Do (b) (4)	28 Oct 2020 15:15:04

US3642035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:52
User entered 'Yes (Y)'	Son Do (b) (4)	28 Oct 2020 15:15:17

US3642035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:52
User entered '26 Oct 2020'	Son Do (b) (4)	28 Oct 2020 15:15:17

US3642035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:26:52
User entered '14:45'	Son Do (b) (4)	28 Oct 2020 15:15:17

US3642035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered '26 Oct 2020 14:45'	System	28 Oct 2020 15:15:17

US3642035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:27:37
User entered 'Yes (Y)'	Son Do (b) (4)	28 Oct 2020 15:15:22

US3642035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	28 Oct 2020 15:15:22

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 64'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-30T12:32:56', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'ae030e36-f5d1-4d89-b961-ae1954a4f37d' User entered 'No (N)'	System	30 Oct 2020 19:33:15
	System	30 Oct 2020 19:33:15

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-30T12:33:03', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'ae030e36-f5d1-4d89-b961-ae1954a4f37d' User entered 'No (N)'	System	30 Oct 2020 19:33:15
	System	30 Oct 2020 19:33:15

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-10-30T12:33:12', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'ae030e36-f5d1-4d89-b961-ae1954a4f37d' User entered '30 Oct 2020 12:33:12'	System	30 Oct 2020 19:33:15
	System	30 Oct 2020 19:33:15

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered '28 Oct 2020 00:01'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered '01 Nov 2020 23:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 71'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-11-06T22:07:39', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '16e06ffb-42ef-4c0a-a512-19b23ba1d437'	System	07 Nov 2020 06:07:52
User entered 'No (N)'	System	07 Nov 2020 06:07:52

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-11-06T22:07:44', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '16e06ffb-42ef-4c0a-a512-19b23ba1d437'	System	07 Nov 2020 06:07:52
User entered 'No (N)'	System	07 Nov 2020 06:07:52

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-11-06T22:07:50', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '16e06ffb-42ef-4c0a-a512-19b23ba1d437'	System	07 Nov 2020 06:07:52
User entered '06 Nov 2020 22:07:50'	System	07 Nov 2020 06:07:52

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered '04 Nov 2020 00:01'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered '08 Nov 2020 23:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered 'Day 78'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-11-11T02:03:10', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'c94d3333-0e32-41b9-b233-c64bf9a899c0' User entered 'No (N)'	System	11 Nov 2020 10:03:24
	System	11 Nov 2020 10:03:24

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-11-11T02:03:15', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'c94d3333-0e32-41b9-b233-c64bf9a899c0' User entered 'No (N)'	System	11 Nov 2020 10:03:24
	System	11 Nov 2020 10:03:24

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8EDA35C1-0C28-45BD-9150-3409AF33A87E)', Time: '2020-11-11T02:03:21', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'c94d3333-0e32-41b9-b233-c64bf9a899c0' User entered '11 Nov 2020 02:03:21'	System	11 Nov 2020 10:03:24
	System	11 Nov 2020 10:03:24

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered '11 Nov 2020 00:01'	System	29 Aug 2020 00:05:07

US3642035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:45:34
Data entry locked.	System	29 Aug 2020 00:05:07
User entered '15 Nov 2020 23:59'	System	29 Aug 2020 00:05:07

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-14T17:30:45', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8d14a763-7df4-485b-9258-d63c156a1aef' User entered 'No (N)'	System	15 Jan 2021 01:30:55
	System	15 Jan 2021 01:30:55

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-14T17:30:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8d14a763-7df4-485b-9258-d63c156a1aef'	System	15 Jan 2021 01:30:55
User entered 'No (N)'	System	15 Jan 2021 01:30:55

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-14T17:30:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8d14a763-7df4-485b-9258-d63c156a1aef' User entered '14 Jan 2021 17:30:53'	System	15 Jan 2021 01:30:55
	System	15 Jan 2021 01:30:55

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-17T11:59:36', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5f7bd309-8972-4248-92a5-907c427e06cd' User entered 'No (N)'	System	18 Jan 2021 00:12:45
	System	18 Jan 2021 00:12:45

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-17T11:59:40', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5f7bd309-8972-4248-92a5-907c427e06cd' User entered 'No (N)'	System	18 Jan 2021 00:12:45
	System	18 Jan 2021 00:12:45

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-17T11:59:44', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5f7bd309-8972-4248-92a5-907c427e06cd' User entered '17 Jan 2021 11:59:44'	System	18 Jan 2021 00:12:45
	System	18 Jan 2021 00:12:45

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-24T06:11:25', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'ab963f9a-779a-4c08-8ce3-5319d2646328' User entered 'No (N)'	System	24 Jan 2021 14:11:37
	System	24 Jan 2021 14:11:37

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-24T06:11:29', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'ab963f9a-779a-4c08-8ce3-5319d2646328' User entered 'No (N)'	System	24 Jan 2021 14:11:37
	System	24 Jan 2021 14:11:37

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-01-24T06:11:34', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'ab963f9a-779a-4c08-8ce3-5319d2646328' User entered '24 Jan 2021 06:11:34'	System	24 Jan 2021 14:11:37
	System	24 Jan 2021 14:11:37

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-01T18:34:22', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'dfa029b1-75cd-4493-a39c-5c1d8dca2789' User entered 'No (N)'	System	02 Feb 2021 02:34:36
	System	02 Feb 2021 02:34:36

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-01T18:34:26', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'dfa029b1-75cd-4493-a39c-5c1d8dca2789' User entered 'No (N)'	System	02 Feb 2021 02:34:36
	System	02 Feb 2021 02:34:36

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-01T18:34:31', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'dfa029b1-75cd-4493-a39c-5c1d8dca2789' User entered '01 Feb 2021 18:34:31'	System	02 Feb 2021 02:34:36
	System	02 Feb 2021 02:34:36

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-07T12:20:53', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f57a0a2c-f4fd-4022-ad4e-3965a9b6579c' User entered 'No (N)'	System	07 Feb 2021 20:21:03
	System	07 Feb 2021 20:21:03

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-07T12:20:57', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f57a0a2c-f4fd-4022-ad4e-3965a9b6579c' User entered 'No (N)'	System	07 Feb 2021 20:21:03
	System	07 Feb 2021 20:21:03

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-07T12:21:01', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'f57a0a2c-f4fd-4022-ad4e-3965a9b6579c' User entered '07 Feb 2021 12:21:01'	System	07 Feb 2021 20:21:03
	System	07 Feb 2021 20:21:03

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:20', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7' User entered 'Yes (Y)'	System	14 Feb 2021 16:00:53
	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:26', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered 'No (N)'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:32', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered 'Yes (Y)'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '1'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '1'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '1'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '1'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '1'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '1'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7' User entered '0'	System	14 Feb 2021 16:00:53
	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7' User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '1'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T07:59:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered '0'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T08:00:14', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T08:00:23', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7' User entered 'Yes (Y)'	System	14 Feb 2021 16:00:53
	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T08:00:27', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7'	System	14 Feb 2021 16:00:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-14T08:00:33', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '3580bdf7-8961-431a-aff9-aaaae2e1d6b7' User entered '14 Feb 2021 08:00:33'	System	14 Feb 2021 16:00:53
	System	14 Feb 2021 16:00:53

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-21T12:18:48', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4021c976-0c5e-4dda-aec4-9e4cd1609f15' User entered 'No (N)'	System	21 Feb 2021 20:25:47
	System	21 Feb 2021 20:25:47

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-21T12:25:35', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4021c976-0c5e-4dda-aec4-9e4cd1609f15' User entered 'No (N)'	System	21 Feb 2021 20:25:47

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-21T12:25:43', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '4021c976-0c5e-4dda-aec4-9e4cd1609f15' User entered '21 Feb 2021 12:25:43'	System	21 Feb 2021 20:25:47
	System	21 Feb 2021 20:25:47

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-01T09:04:21-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a5d0b94d-dff8-4890-9fc6-714e735cfe90'	System	01 Mar 2021 17:17:16
User entered 'No (N)'	System	01 Mar 2021 17:17:16

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-01T09:04:24-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a5d0b94d-dff8-4890-9fc6-714e735cfe90'	System	01 Mar 2021 17:17:16
User entered 'No (N)'	System	01 Mar 2021 17:17:16

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-01T09:04:27-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'a5d0b94d-dff8-4890-9fc6-714e735cfe90'	System	01 Mar 2021 17:17:16
User entered '01 Mar 2021 09:04:27'	System	01 Mar 2021 17:17:16

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-07T06:24:27-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '252c87d1-a58e-44ae-beb5-be87aad347a0'	System	07 Mar 2021 14:24:39
User entered 'No (N)'	System	07 Mar 2021 14:24:39

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-07T06:24:30-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '252c87d1-a58e-44ae-beb5-be87aad347a0'	System	07 Mar 2021 14:24:39
User entered 'No (N)'	System	07 Mar 2021 14:24:39

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-07T06:24:34-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '252c87d1-a58e-44ae-beb5-be87aad347a0' User entered '07 Mar 2021 06:24:34'	System	07 Mar 2021 14:24:39
	System	07 Mar 2021 14:24:39

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-14T17:25:58-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'cd60ee22-1ecb-4abe-8e5d-f6ce6796885f' User entered 'No (N)'	System	15 Mar 2021 00:26:10
	System	15 Mar 2021 00:26:10

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-14T17:26:01-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'cd60ee22-1ecb-4abe-8e5d-f6ce6796885f'	System	15 Mar 2021 00:26:10
User entered 'No (N)'	System	15 Mar 2021 00:26:10

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-14T17:26:07-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'cd60ee22-1ecb-4abe-8e5d-f6ce6796885f' User entered '14 Mar 2021 17:26:07'	System	15 Mar 2021 00:26:10
	System	15 Mar 2021 00:26:10

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-21T13:26:12-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'df3a1240-9129-4d17-a2a0-a158b9e74b9e'	System	21 Mar 2021 20:26:26
User entered 'No (N)'	System	21 Mar 2021 20:26:26

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-21T13:26:16-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'df3a1240-9129-4d17-a2a0-a158b9e74b9e'	System	21 Mar 2021 20:26:26
User entered 'No (N)'	System	21 Mar 2021 20:26:26

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-21T13:26:20-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: 'df3a1240-9129-4d17-a2a0-a158b9e74b9e' User entered '21 Mar 2021 13:26:20'	System	21 Mar 2021 20:26:26
	System	21 Mar 2021 20:26:26

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-28T06:11:45-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '2cd20b31-4087-40cf-87b4-6d60cd7af91b'	System	28 Mar 2021 13:11:57
User entered 'No (N)'	System	28 Mar 2021 13:11:57

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-28T06:11:50-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '2cd20b31-4087-40cf-87b4-6d60cd7af91b'	System	28 Mar 2021 13:11:57
User entered 'No (N)'	System	28 Mar 2021 13:11:57

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-03-28T06:11:55-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '2cd20b31-4087-40cf-87b4-6d60cd7af91b' User entered '28 Mar 2021 06:11:55'	System	28 Mar 2021 13:11:57
	System	28 Mar 2021 13:11:57

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-04T09:43:12-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '76f63faf-255d-4e71-b582-35bc7f8d078d'	System	04 Apr 2021 16:43:23
User entered 'No (N)'	System	04 Apr 2021 16:43:23

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-04T09:43:16-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '76f63faf-255d-4e71-b582-35bc7f8d078d'	System	04 Apr 2021 16:43:23
User entered 'No (N)'	System	04 Apr 2021 16:43:23

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-04T09:43:20-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '76f63faf-255d-4e71-b582-35bc7f8d078d'	System	04 Apr 2021 16:43:23
User entered '04 Apr 2021 09:43:20'	System	04 Apr 2021 16:43:23

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-11T06:13:15-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '89fd2f55-4fe1-4411-9786-749019ada76f'	System	11 Apr 2021 13:13:27
User entered 'No (N)'	System	11 Apr 2021 13:13:27

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-11T06:13:20-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '89fd2f55-4fe1-4411-9786-749019ada76f' User entered 'No (N)'	System	11 Apr 2021 13:13:27
	System	11 Apr 2021 13:13:27

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-11T06:13:24-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '89fd2f55-4fe1-4411-9786-749019ada76f'	System	11 Apr 2021 13:13:27
User entered '11 Apr 2021 06:13:24'	System	11 Apr 2021 13:13:27

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-18T11:54:34-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '046d4f06-e586-4eec-b661-e8ab33ea94d2'	System	18 Apr 2021 18:54:43
User entered 'No (N)'	System	18 Apr 2021 18:54:43

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-18T11:54:37-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '046d4f06-e586-4eec-b661-e8ab33ea94d2' User entered 'No (N)'	System	18 Apr 2021 18:54:43

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-18T11:54:40-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '046d4f06-e586-4eec-b661-e8ab33ea94d2'	System	18 Apr 2021 18:54:43
User entered '18 Apr 2021 11:54:40'	System	18 Apr 2021 18:54:43

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-25T15:37:39-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ab7e2eb-64f7-4716-90ac-e87c100f1026'	System	25 Apr 2021 22:37:51
User entered 'No (N)'	System	25 Apr 2021 22:37:51

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

Have you been exposed to someone with 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 (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-25T15:37:43-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ab7e2eb-64f7-4716-90ac-e87c100f1026'	System	25 Apr 2021 22:37:51
User entered 'No (N)'	System	25 Apr 2021 22:37:51

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-04-25T15:37:47-07:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '8ab7e2eb-64f7-4716-90ac-e87c100f1026'	System	25 Apr 2021 22:37:51
User entered '25 Apr 2021 15:37:47'	System	25 Apr 2021 22:37:51

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 20:23:21

US3642035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:23:21
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 20:23:21

US3642035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:11:03

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 01:20:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-27T16:33:51-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5820d26b-4612-4212-aa40-1f73f988d0c7'	System	28 Feb 2021 00:33:59
User entered 'No (N)'	System	28 Feb 2021 00:33:59

US3642035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:11:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:20:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FD928B1-CF49-42D5-AEB7-B819FEB28957)', Time: '2021-02-27T16:33:56-08:00', User OID: 'PatientReportedOutcome (US3642035)', ODM File OID: '5820d26b-4612-4212-aa40-1f73f988d0c7' User entered '28 Feb 2021 00:33:56'	System	28 Feb 2021 00:33:59
	System	28 Feb 2021 00:33:59

US3642035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 23:51:52
DataPoint Un-verified.		18 Dec 2020 22:18:19
DataPoint Verified.		18 Dec 2020 22:18:01
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	23 Nov 2020 18:05:09
	(b) (4)	

US3642035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 23:51:52
Query 'Date of Contact: verify with source data.' canceled (Site from CRA).		20 Feb 2021 19:14:54
User opened query 'Date of Contact: verify with source data.' (Site from CRA).		18 Dec 2020 22:19:05
DataPoint Un-verified.		18 Dec 2020 22:18:21
DataPoint Verified.		18 Dec 2020 22:18:01
User entered '23 Nov 2020'	Jennifer Morales (b) (4)	23 Nov 2020 18:05:09
	(b) (4)	

US3642035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 23:51:52
DataPoint Un-verified.		18 Dec 2020 22:18:22
DataPoint Verified.		18 Dec 2020 22:18:01
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	23 Nov 2020 18:05:09
	(b) (4)	

US3642035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 23:51:52
DataPoint Un-verified.		18 Dec 2020 22:18:24
DataPoint Verified.		18 Dec 2020 22:18:01
User entered empty.	Jennifer Morales (b) (4)	23 Nov 2020 18:05:09
	(b) (4)	

US3642035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 22:45:29
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	23 Nov 2020 18:05:14

US3642035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:04:47
User entered 'I'	System	23 Nov 2020 18:05:14

US3642035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:52:43
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	06 Jan 2021 20:55:55

US3642035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:52:43
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '06 Jan 2021'	(b) (4) Jennifer Morales (b) (4) (b) (4)	06 Jan 2021 20:55:55

US3642035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:52:43
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	06 Jan 2021 20:55:55

US3642035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:52:43
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered empty.	(b) (4) Jennifer Morales (b) (4) (b) (4)	06 Jan 2021 20:55:55

US3642035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:52:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	06 Jan 2021 20:56:00

US3642035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User entered 'I'	System	06 Jan 2021 20:56:00

US3642035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:54:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	25 Jan 2021 19:01:00

US3642035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:54:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '21 Jan 2021'	(b) (4) Lindsey Woronicz (b) (4)	25 Jan 2021 19:01:00

US3642035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:54:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	25 Jan 2021 19:01:00

US3642035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:54:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	25 Jan 2021 19:01:00

US3642035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
DataPoint Verified.		25 Feb 2021 23:54:27
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
User entered 'Yes (Y)'	Lindsey Woronicz (b) (4)	25 Jan 2021 19:01:05

US3642035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User entered 'I'	System	25 Jan 2021 19:01:05

US3642035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:54:49
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	24 Feb 2021 01:05:52

US3642035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:54:49
User entered '23 Feb 2021'	Jennifer Morales (b) (4) (b) (4)	24 Feb 2021 01:05:52

US3642035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:54:49
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4) (b) (4)	24 Feb 2021 01:05:52

US3642035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:54:49
User entered empty.	Jennifer Morales (b) (4) (b) (4)	24 Feb 2021 01:05:52

US3642035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:54:53
User entered 'Yes (Y)'	Jennifer Morales (b) (4) (b) (4)	24 Feb 2021 01:05:58

US3642035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:18:24
User entered 'I'	System	24 Feb 2021 01:05:58

US3642035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:48:38
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	20 Apr 2021 17:22:34

US3642035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:22:34

US3642035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:48:38
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	20 Apr 2021 17:22:54

US3642035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:48:38
	(b) (4)	
User entered '20 Apr 2021'	Nancy Tang (b) (4)	20 Apr 2021 17:22:54

US3642035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:48:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	20 Apr 2021 17:22:54

US3642035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:48:38
User entered empty.	(b) (4) Nancy Tang (b) (4)	20 Apr 2021 17:22:54

US3642035

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:48:38
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	20 Apr 2021 17:23:00

US3642035

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 17:23:00

US3642035

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:55:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:35:57

US3642035

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:55:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '14 Jan 2021'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:35:57

US3642035

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[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 03:04:54
DataPoint Verified.		25 Feb 2021 23:55:24
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:35:57

US3642035

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

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 17:35:57

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:56:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '14 Jan 2021'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:57:04

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:56:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:57:04

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	25 Feb 2021 23:56:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 09:16:25
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Data are correct. Subject unblinding occurred prior to date of consent form. PD reported.' (Site from System).	Colleen McLellan (b) (4) (b) (4)	26 Jan 2021 22:33:54
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	19 Jan 2021 17:36:15
User entered '08 Jan 2021'	Son Do (b) (4)	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:56:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Placebo (Placebo)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:56:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:20:42
User entered 'Placebo (Placebo)'	Son Do (b) (4)	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:56:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:20:42
User entered 'Placebo (Placebo)'	Son Do (b) (4)	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:56:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '1'	System	19 Jan 2021 17:36:15

US3642035

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

Form: Unblinding

Generated On: 10 Jun 2021 09:11:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'I'	System	19 Jan 2021 17:36:15

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	19 Jan 2021 17:36:58
DataPoint set to visible.	System	19 Jan 2021 17:36:15

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	19 Jan 2021 17:36:58
DataPoint set to visible.	System	19 Jan 2021 17:36:15

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '14 Jan 2021'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '15:31'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '14 Jan 2021 15:31'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '97.3' F	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered 'Oral (Oral)'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered empty.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '62'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'bpm'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '16'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'breaths/min'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '115'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 23:57:31
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).		23 Feb 2021 04:13:27
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 'DIASTOLIC BP NCS' (Site from System).	Colleen McLellan (b) (4)	22 Feb 2021 19:02:52
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		19 Jan 2021 17:36:58
User entered '58'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered missing code ND - Not Done.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:11:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	19 Jan 2021 17:36:58
DataPoint set to visible.	System	19 Jan 2021 17:36:15

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '14 Jan 2021'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '17:24'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '14 Jan 2021 17:24'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '97.8' F	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered 'Oral (Oral)'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered empty.	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '58'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'bpm'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '16'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'breaths/min'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '117'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 23:57:31
User entered '60'	Son Do (b) (4)	19 Jan 2021 17:36:58

US3642035

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	19 Jan 2021 17:36:58

US3642035

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	25 Feb 2021 23:57:43
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'No (N)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:04

US3642035

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:57:43
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered empty.	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:04

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:57:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:57:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered empty.	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

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 03:04:54
DataPoint Verified.		25 Feb 2021 23:57:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered empty.	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mRNA-1273'	System	19 Jan 2021 17:37:18
DataPoint set to visible.	System	19 Jan 2021 17:36:15

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:57:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '14 Jan 2021'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	25 Feb 2021 23:57:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '16:50'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '14 Jan 2021 16:50'	System	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:57:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:57:57
User entered 'ONCE'	System	19 Jan 2021 17:37:18

US3642035

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

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 17:37:18

US3642035

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	25 Feb 2021 23:58:06
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:29

US3642035

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:06
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '14 Jan 2021'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:29

US3642035

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:06
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '16:25'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:29

US3642035

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '14 Jan 2021 16:25'	System	19 Jan 2021 17:37:29

US3642035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:40

US3642035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '14 Jan 2021'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:40

US3642035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '16:29'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:40

US3642035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:11:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '14 Jan 2021 16:29'	System	19 Jan 2021 17:37:40

US3642035

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

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:16
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	19 Jan 2021 17:37:45

US3642035

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

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'I'	System	19 Jan 2021 17:37:45

US3642035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	21 Jan 2021 21:24:08

US3642035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '21 Jan 2021'	(b) (4) Jennifer Morales (b) (4) (b) (4)	21 Jan 2021 21:24:08

US3642035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	21 Jan 2021 21:24:08

US3642035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered empty.	(b) (4) Jennifer Morales (b) (4) (b) (4)	21 Jan 2021 21:24:08

US3642035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Feb 2021 23:58:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	21 Jan 2021 21:24:13

US3642035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'I'	System	21 Jan 2021 21:24:13

US3642035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '1'	System	21 Jan 2021 21:24:13
DataPoint set to visible.	System	21 Jan 2021 21:24:13

US3642035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:25
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:43:25

US3642035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:25
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered '11 Feb 2021'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:43:25

US3642035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[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 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:25
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:43:25

US3642035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'OLD29'	System	16 Feb 2021 16:43:25

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '11 Feb 2021'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '13:28'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '11 Feb 2021 13:28'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '98.2' F	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered empty.	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '64'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'bpm'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '16'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'breaths/min'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '120'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	23 Feb 2021 04:12:55
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'DIASTOLIC BP NCS' (Site from System).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:04:50
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).		16 Feb 2021 16:44:06
User entered '54'	Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:11:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '11 Feb 2021'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '15:18'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '11 Feb 2021 15:18'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '98.1' F	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered empty.	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '63'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'bpm'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '16'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'breaths/min'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '108'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '63'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mmHg'	System	16 Feb 2021 16:44:06

US3642035

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:30
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'No (N)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:13

US3642035

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:30
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered empty.	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:13

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:38
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:38
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered empty.	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

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 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:38
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered empty.	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'mRNA-1273'	System	16 Feb 2021 16:44:31
DataPoint set to visible.	System	21 Jan 2021 21:24:13

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:38
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered '11 Feb 2021'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:35:38
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered '14:40'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '11 Feb 2021 14:40'	System	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:35:38
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:38
User entered 'ONCE'	System	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:11:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 16:44:31

US3642035

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:35:41
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	16 Feb 2021 16:44:38

US3642035

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'I'	System	16 Feb 2021 16:44:38

US3642035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Mar 2021 20:13:14
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	18 Feb 2021 17:45:10

US3642035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Mar 2021 20:13:14
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered '18 Feb 2021'	(b) (4) Jennifer Morales (b) (4) (b) (4)	18 Feb 2021 17:45:10

US3642035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Mar 2021 20:13:14
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	18 Feb 2021 17:45:10

US3642035

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Mar 2021 20:13:14
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered empty.	(b) (4) Jennifer Morales (b) (4) (b) (4)	18 Feb 2021 17:45:10

US3642035

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		25 Mar 2021 20:13:17
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:02:42
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4) (b) (4)	18 Feb 2021 17:45:15

US3642035

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:11:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'I'	System	18 Feb 2021 17:45:15

US3642035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:33:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:00

US3642035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:33:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered '10 Mar 2021'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:00

US3642035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[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 03:04:54
DataPoint Verified.		24 Mar 2021 21:33:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:00

US3642035

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered 'OLD57'	System	11 Mar 2021 16:57:00

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered 'No (N)'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	11 Mar 2021 16:57:13

US3642035

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		24 Mar 2021 21:34:00
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:13

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered empty.	System	11 Mar 2021 16:57:13

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		07 Apr 2021 19:43:01
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered 'No (N)'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:20

US3642035

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.		07 Apr 2021 19:43:01
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered empty.	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:20

US3642035

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:34:07
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:36

US3642035

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:34:07
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered '10 Mar 2021'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:36

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
DataPoint Verified.	(b) (4)	24 Mar 2021 21:34:07
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:10:42
User entered '15:43'	(b) (4) Son Do (b) (4)	11 Mar 2021 16:57:36

US3642035

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:11:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:04:54
User entered '10 Mar 2021 15:43'	System	11 Mar 2021 16:57:36

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:11:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:42
User closed query 'Per DM CLR: Per Day 173 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).		26 Mar 2021 12:16:43
Query 'Per DM CLR: Per Day 173 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'No corresponding AE for this recorded data. Patient contacted by study staff and no s/s COVID-19 to be reported. ' (Site from DM). DataPoint Verified.	Colleen McLellan (b) (4) (b) (4)	25 Mar 2021 19:21:24
User opened query 'Per DM CLR: Per Day 173 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 21:34:25
User signature succeeded.		22 Mar 2021 14:30:07
DataPoint Un-verified.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:25:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	20 Nov 2020 02:55:21
DataPoint Verified.	Nancy Tang (b) (4) (b) (4), (b) (6)	20 Nov 2020 02:55:21
User entered 'No (N)'	(b) (4), (b) (6) Megan Loughran (b) (4) (b) (4)	06 Nov 2020 20:53:51
		01 Sep 2020 06:43:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'For coding purposes, please split LOWER BACK LEFT FLANK PAIN W/ MUSCLE SPASM AND NAUSEA into separate entries. ' (Site from Coder).		14 Mar 2021 17:16:33
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: Flank pain, LLT: Flank pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:59:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:59:01
Query 'For coding purposes, please split LOWER BACK LEFT FLANK PAIN W/ MUSCLE SPASM AND NAUSEA into separate entries. ' answered with 'UPDATED IN SEPARATE AES' (Site from Coder).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:58:32
Data point term sent to Coder	System	22 Feb 2021 18:58:17
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:57:26
User entered 'FLANK PAIN (LEFT)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:57:26
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: Flank pain, LLT: Flank pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:25
User opened query 'For coding purposes, please split LOWER BACK LEFT FLANK PAIN W/ MUSCLE SPASM AND NAUSEA into separate entries. ' (Site from Coder).	(b) (4), (b) (6)	20 Dec 2020 19:30:17
Data point term sent to Coder	System	18 Dec 2020 16:40:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'LOWER BACK LEFT FLANK PAIN W/ MUSCLE SPASM and nausea' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 16:39:42
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	18 Dec 2020 16:30:17
	Megan Loughran (b) (4)	18 Dec 2020 16:30:08
	(b) (4)	
User entered 'LOWER BACK LEFT FLANK PAIN w/ muscle spasm' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 16:30:08
	(b) (4)	
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: Flank pain, LLT: Flank pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 03:42:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 03:42:52
	(b) (4)	
Data point term sent to Coder	System	20 Nov 2020 03:00:10
User entered 'Lower back left flank pain'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '31 Aug 2020'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Nov 2020 03:01:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 03:01:12
User entered empty; reason for change Data Entry Error	Nancy Tang (b) (4)	20 Nov 2020 03:01:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 03:00:59
User entered 'un:un' (non-conformant).	Nancy Tang (b) (4)	20 Nov 2020 03:00:59
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Nov 2020 03:00:05
User entered '09:00'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User entered empty.	System	20 Nov 2020 03:01:12
User entered '31 Aug 2020 UN:UN' (non-conformant).	System	20 Nov 2020 03:00:59
User entered '31 Aug 2020 09:00'	System	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '03 Sep 2020' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:57:26
User entered '01 Sep 2020'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	20 Nov 2020 03:00:59
User entered empty; reason for change Data Entry Error	Nancy Tang (b) (4)	20 Nov 2020 03:00:59
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	20 Nov 2020 03:00:05
User entered '21:00'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User entered empty.	System	20 Nov 2020 03:00:59
User entered '01 Sep 2020 21:00'	System	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).		05 Jan 2021 03:43:54
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'Start date is between first and second dose of investigational product. Action taken "none" is correct. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Jan 2021 19:20:11
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:34:23
User entered 'None (NONE)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '1' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 16:17:00
User entered '0'	(b) (4) Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'Per DM CLR: RQ: Response noted, however, there is no therapeutic procedure for this AE recorded in the Con Proc eCRF. Review response and record a therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: RQ: Response noted, however, there is no therapeutic procedure for this AE recorded in the Con Proc eCRF. Review response and record a therapeutic procedure as appropriate. Otherwise, clarify.' answered with 'NO THERAPEUTIC PROCEDURES REPORTED, ONLY DIAGNOSTIC. WILL UNCHECK CON-PROCEDURE BOX ' (Site from DM).	(b) (4)	23 Feb 2021 17:07:05
User entered '0' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:59:05
User opened query 'Per DM CLR: RQ: Response noted, however, there is no therapeutic procedure for this AE recorded in the Con Proc eCRF. Review response and record a therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:58:23
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:33:13
User closed query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:53:39
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	21 Dec 2020 08:52:55
		18 Dec 2020 16:17:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.' answered with 'added' (Site from DM).	Megan Loughran (b) (4)	18 Dec 2020 16:16:43
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 03:18:53
User opened query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 09:28:29
User entered 'I'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	20 Nov 2020 03:01:37
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	20 Nov 2020 03:00:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty; reason for change Data Entry Error	Nancy Tang (b) (4)	20 Nov 2020 03:01:37
User entered 'All labs CXR normal. Subject reports feeling completely back to normal at 36 hours.'	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'Per DM CLR: Narrative indicates that subject had "LABS and CHEST XRAY". However, these are not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Narrative indicates that subject had "LABS and CHEST XRAY". However, these are not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify.' answered with 'added' (Site from DM).	(b) (4)	22 Dec 2020 04:01:17
User opened query 'Per DM CLR: Narrative indicates that subject had "LABS and CHEST XRAY". However, these are not recorded in the Concomitant Procedure eCRF. Please review and record as appropriate. Otherwise, clarify.' (Site from DM).	Megan Loughran (b) (4)	18 Dec 2020 16:17:09
User entered 'SUBJECT REPORTS 10/10 LEFT FLANK/LOWER BACK AND WENT TO ED RULED OUT KIDNEY STONE, NO DISSECTION, ASSUMED IT WAS MUSCLE STRAIN, IMPROVED TO 2/10 ABOUT 24 HOURS LATER. ALL LABS, Chest xray NORMAL. COMPLETELY BACK TO NORMAL AT 36 HOURS. SUBJECT WILL CONTINUE TO REMAIN ON STUDY.'	(b) (4), (b) (6)	12 Dec 2020 03:18:59
reason for change: Data Entry Error		
User entered 'Subject reports 10/10 left flank/lower back and went to ED ruled out kidney stone, no dissection, assumed it was muscle strain, improved to 2/10 about 24 hours later. All labs CXR normal. Completely back to normal at 36 hours. Subject will continue to remain on study.'	Nancy Tang (b) (4)	20 Nov 2020 03:02:38
	Nancy Tang (b) (4)	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User entered '0'	System	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32
User entered 'I'	System	20 Nov 2020 03:00:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:33:44
Data point term sent to Coder	System	18 Dec 2020 16:27:14
User entered 'dehydration'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

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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)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User entered empty.	System	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User entered empty.	System	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
Query 'Per CDM:Requery:Response noted,however as per CCG V4.0 pg 47,If AE started and ended during a time period when study dose was interrupted, "Not Applicable" should be used. Kindly update accordingly. Thank you. ' canceled (Site from DM).		07 Jan 2021 13:47:33
User opened query 'Per CDM:Requery:Response noted,however as per CCG V4.0 pg 47,If AE started and ended during a time period when study dose was interrupted, "Not Applicable" should be used. Kindly update accordingly. Thank you. ' (Site from DM).		05 Jan 2021 03:29:58
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).		05 Jan 2021 03:25:47
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'AE start date is between first and second dose of investigational product. Action taken "none" is correct. ' (Site from DM).	Colleen McLellan (b) (4)	04 Jan 2021 19:21:08
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:36:49
User entered 'None (NONE)'	Megan Loughran (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'l'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'while in ED for flank pain, clinician observed mild dehydration in pt. treated w/ IV fluids. pt recovered prior to discharge w/o sequellae'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User entered '0'	System	18 Dec 2020 16:26:33

US3642035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35
User entered 'I'	System	18 Dec 2020 16:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:02
Data point term sent to Coder	System	18 Dec 2020 16:59:40
User entered 'osteopenia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '03 Sep 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 16:59:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

US3642035

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4)	05 Jan 2021 03:41:53
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'AE start date is between first and second dose of investigational product. Action taken "none" is correct. ' (Site from DM).	Colleen McLellan (b) (4)	04 Jan 2021 19:21:47
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:37:42
User entered 'None (NONE)'	Megan Loughran (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

None

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 16:59:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'I'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 16:59:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'pt diagnosed w/ osteopenia by pmd. ongoing at this time. treated w/ fosamax.'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Dec 2020 16:59:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:39:49
User entered	System	21 Dec 2020 15:35:13
'USA-US109-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	21 Dec 2020 15:35:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'For coding purposes, TOTAL HIP REPLACEMENT, LEFT, SCHEDULED PLANNED PROCEDURE is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).		14 Mar 2021 17:19:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:17:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:17:57
Query 'For coding purposes, TOTAL HIP REPLACEMENT, LEFT, SCHEDULED PLANNED PROCEDURE is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'UPDATED TO: WORSENING OSTEOARTHRITIS OF LEFT HIP WITH CON PROCEDURE OF TOTAL LEFT HIP REPLACEMENT ' (Site from Coder).	Colleen McLellan (b) (4)	22 Feb 2021 17:23:13
Data point term sent to Coder	System	22 Feb 2021 17:21:09
User entered 'WORSENING OSTEOARTHRITIS LEFT HIP' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:20:26
Data point term sent to Coder	System	22 Feb 2021 17:01:50
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 17:01:41
User entered 'TOTAL HIP REPLACEMENT, LEFT' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:01:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthropathy, LLT: Hip arthropathy - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 15:26:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 15:26:42

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:05
User opened query 'For coding purposes, TOTAL HIP REPLACEMENT, LEFT, SCHEDULED PLANNED PROCEDURE is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6) (b) (4)	20 Dec 2020 19:29:33
Data point term sent to Coder	System	18 Dec 2020 17:41:09
User entered 'total hip replacement, left, scheduled planned procedure.'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		22 Feb 2021 17:22:43
User closed query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		22 Feb 2021 17:22:43
User entered '10 Sep 2020' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 17:22:43
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	22 Feb 2021 17:20:26
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		22 Feb 2021 17:20:26
User entered '10 Aug 2020' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 17:20:26
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 17:20:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:41:13
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '12 Oct 2020' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:20:26
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Dec 2020 17:41:13
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 17:40:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	18 Dec 2020 17:40:57
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Dec 2020 17:40:57
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 17:40:57
	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 17:40:32
User entered '13 Oct 2020'	Megan Loughran (b) (4)	18 Dec 2020 17:40:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		22 Feb 2021 21:27:25
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'END DATE PROVIDED' (Site from Safety).	Colleen McLellan (b) (4)	22 Feb 2021 17:23:30
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:34:16
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 17:40:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

US3642035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

US3642035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

US3642035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'I'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:44:40
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'hospital discharge summary sent 25MAR2021 at 1208' (Site from Safety).	Colleen McLellan (b) (4) (b) (4)	25 Mar 2021 19:09:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		04 Mar 2021 14:30:33
User entered '13 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

US3642035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

US3642035

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 17:40:32
	(b) (4)	

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 17:40:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Applicable (NOT APPLICABLE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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None

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 17:40:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'I'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'I'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		22 Feb 2021 21:27:48
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'OSTEOARTHRITIS RECOVERED/RESOLVED AFTER TOTAL HIP REPLACEMENT ' (Site from Safety).	Colleen McLellan (b) (4)	22 Feb 2021 17:24:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:33:57
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Megan Loughran (b) (4)	18 Dec 2020 17:40:32
	(b) (4)	

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Form: Adverse Events (4)

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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)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
User closed query 'PV Query: Based upon information of concomitant medications, pain, nausea, muscle spasms, and dehydration were treated on 31-Aug-2020 and 01-Sep-2020. Please provide the clinical profile of these symptoms, and clarify whether these meet criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:45:13
User closed query 'PV Query: Please confirm there was exacerbation of a pre-existing osteoarthritis or another condition. If not, please reconsider whether the event meets criteria of AE/SAE.'		26 Mar 2021 18:44:58
(Site from Safety).		
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		26 Mar 2021 18:44:48
Query 'PV Query: Based upon information of concomitant medications, pain, nausea, muscle spasms, and dehydration were treated on 31-Aug-2020 and 01-Sep-2020. Please provide the clinical profile of these symptoms, and clarify whether these meet criteria of AE/SAE.' answered with 'This query is not associated with AE it is located on. It is assumed that you are inquiring about AEs 1, 2, 5, 6 - in which patient was seen in the ER and treated for flank pain, nausea, muscle spasms, and dehydration. Treatment in the ER lasted from 31AUG2020-01SEP2020 but the patient was not admitted inpatient therefore no SAE required. Although treatment spanned into 2 calendar days the patient did not have 2 ER encounters. AE's already reported and referenced above. Additional information regarding each symptom and clinical course is provided in their individual AE narrative. '	Colleen McLellan (b) (4)	25 Mar 2021 19:20:14
(Site from Safety).	(b) (4)	
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with ' No relevant laboratory/diagnostic test results to provide' (Site from Safety).	Colleen McLellan (b) (4)	25 Mar 2021 19:10:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm there was exacerbation of a pre-existing osteoarthritis or another condition. If not, please reconsider whether the event meets criteria of AE/SAE. ' answered with 'Confirmed – patient experienced worsening osteoarthritis which then required total left hip replacement. Osteoarthritis reported in MH at enrollment (see log line 3).' (Site from Safety). DataPoint Verified.	Colleen McLellan (b) (4)	25 Mar 2021 19:10:07
User opened query 'PV Query: Based upon information of concomitant medications, pain, nausea, muscle spasms, and dehydration were treated on 31-Aug-2020 and 01-Sep-2020. Please provide the clinical profile of these symptoms, and clarify whether these meet criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 21:34:46
User opened query 'PV Query: Please confirm there was exacerbation of a pre-existing osteoarthritis or another condition. If not, please reconsider whether the event meets criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:21:15
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:20:32
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:19:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:29:11
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:28:13
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:28:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'DISCHARGE SUMMARY PRINTED - WILL REDACT PATIENT IDENTIFIERS AND SEND ' (Site from Safety).	Colleen McLellan (b) (4)	22 Feb 2021 17:35:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'RELEVANT LABS AND DIAGNOSTIC RESULTS INCLUDED IN HOSPITAL SUMMARY IN CHART' (Site from Safety).	Colleen McLellan (b) (4)	22 Feb 2021 17:34:30
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID TEST 11OCT2020 NEGATIVE ' (Site from Safety).	Colleen McLellan (b) (4)	22 Feb 2021 17:24:11
User entered 'PATIENT UNDERWENT TOTAL LEFT HIP REPLACEMENT FOR WORSENING OSTEOARTHRITIS OF THE LEFT HIP ON 12OCT2020. sHE HAD A COVID TEST ON 11OCT2020 PRIOR TO HER PROCEDURE AND WAS NEGATIVE. SHE WAS HOSPITALIZED OVERNIGHT POST-PROCEDURE. SHE HAS MADE A FULL RECOVERY AND WILL REMAIN ON STUDY.' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:21:44
User entered 'PATIENT UNDERWENT TOTAL LEFT HIP REPLACEMENT FOR WORSENING OSTEOARTHRITIS OF THE LEFT HIP. SHE WAS HOSPITALIZED OVERNIGHT POST-PROCEDURE. SHE HAS MADE A FULL RECOVERY AND WILL REMAIN ON STUDY.' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:20:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:33:40

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:33:28
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).		23 Dec 2020 14:33:15
User entered 'this was a planned total hip replacement subsequent to pt's ongoing history of osteoarthritis. Patient did not experience any complications and was discharged as scheduled. patient is recovering as expected.'	Megan Loughran (b) (4)	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Dec 2020 17:40:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 23:38:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 23:38:47
Data point term sent to Coder	System	22 Feb 2021 19:01:21
User entered 'MUSCLE SPASMS (LEFT BACK)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

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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)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '31 Aug 2020'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User entered empty.	System	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '03 Sep 2020'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User entered empty.	System	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'None (NONE)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'l'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Subject reports 10/10 left flank pain and went to ED to rule out kidney stone. No dissection found and it was assumed to be muscle strain d/t lifting heavy items while helping her sister move. She experienced left sided muscle spasms in her back and nausea while in the ED. All labs, CXR, chest CT, and abd/pelvic CT WNL. She reports being back to baseline within 36 hours. SHE WILL REMAIN ON STUDY.'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:01:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User entered '0'	System	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42
User entered 'I'	System	22 Feb 2021 19:01:10

US3642035

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:42

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
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)	22 Feb 2021 19:03:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 19:03:00
Data point term sent to Coder	System	22 Feb 2021 19:02:21
User entered 'NAUSEA'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '31 Aug 2020'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User entered empty.	System	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '03 Sep 2020'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User entered empty.	System	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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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)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'None (NONE)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'l'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered '0'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered empty.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:34:46
User entered 'Subject reports 10/10 left flank pain and went to ED to rule out kidney stone. No dissection found and it was assumed to be muscle strain d/t lifting heavy items while helping her sister move. She experienced left sided muscle spasms in her back and nausea while in the ED. All labs, CXR, chest CT, and abd/pelvic CT WNL. She reports being back to baseline within 36 hours. SHE WILL REMAIN ON STUDY.'	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User entered '0'	System	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49
User entered 'I'	System	22 Feb 2021 19:02:01

US3642035

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:11:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:11:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User closed query 'Per CDM: Response noted on Diary Dose 1 form. However, there is no corresponding conmed recorded for day4 (01SEP2020) and day5 (02SEP2020). Please confirm if medication was taken and update the Conmed as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM). Query 'Per CDM: Response noted on Diary Dose 1 form. However, there is no corresponding conmed recorded for day4 (01SEP2020) and day5 (02SEP2020). Please confirm if medication was taken and update the Conmed as appropriate, or if medication is already recorded, please provide log line number.' answered with 'added' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 08:56:44
User opened query 'Per CDM: Response noted on Diary Dose 1 form. However, there is no corresponding conmed recorded for day4 (01SEP2020) and day5 (02SEP2020). Please confirm if medication was taken and update the Conmed as appropriate, or if medication is already recorded, please provide log line number.'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:34:02
User opened query 'Per CDM: Response noted on Diary Dose 1 form. However, there is no corresponding conmed recorded for day4 (01SEP2020) and day5 (02SEP2020). Please confirm if medication was taken and update the Conmed as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:12:57
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:08:24
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:43:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:13:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:57:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:57:38
Data point term sent to Coder	System	01 Sep 2020 06:45:09
User entered 'apixaban'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:13:35
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:13:36
User entered 'atrial fibrillation'	Megan Loughran (b) (4)	01 Sep 2020 06:44:59
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:13:38
User entered '5'	Megan Loughran (b) (4)	01 Sep 2020 06:44:59
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:13:39
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	01 Sep 2020 06:44:59
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:13:41
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User closed query 'Per source route of administration is not documented. Please reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 00:05:03
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:29:22
Query 'Per source route of administration is not documented. Please reconcile. ' answered with 'added (Site from CRA).	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 18:52:27
User opened query 'Per source route of administration is not documented. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 22:14:52
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	01 Sep 2020 06:44:59
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:14:55
User entered 'UN May 2018'	Megan Loughran (b) (4)	01 Sep 2020 06:44:59
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4)	01 Sep 2020 06:44:59
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:14:57
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:14:58
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 06:44:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:14
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.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:46:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:46:48
Data point term sent to Coder	System	01 Sep 2020 06:46:09
User entered 'atorvastatin'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:15
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:17
User entered 'hyperlipidemia'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:19
User entered '10'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:20
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:39:47
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:31
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:39:50
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:02
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:04
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:43
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Sep 2020 06:46:19
User entered 'UN May 2018' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:46:19
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Sep 2020 06:45:42
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:39:38
User entered '0'	Megan Loughran (b) (4)	01 Sep 2020 06:45:42
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:45
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:39:40
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	01 Sep 2020 06:46:19
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:46:19
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	01 Sep 2020 06:45:42
User entered 'UN May 2018'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:15:47
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 06:45:42

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:18:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 07:53:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 07:53:39
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 06:48:10
User entered 'metropolol'	Megan Loughran (b) (4)	01 Sep 2020 06:47:16
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:37
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:40
User entered 'atrial fibrillation, hypertension'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:41
User entered '10'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:43
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:40:10
User entered empty.	Megan Loughran (b) (4)	01 Sep 2020 06:47:16
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:46
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:13
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:15
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:17
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:48
User entered 'UN May 2018'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:19
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:50
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:21
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:51
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 06:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:18:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:48:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 06:48:39
Data point term sent to Coder	System	01 Sep 2020 06:48:11
User entered 'sumatriptan'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:02
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:05
User entered 'migraines'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:07
User entered '100'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:08
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:27
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:19:11
User entered 'as needed (PRN)'	Megan Loughran (b) (4)	01 Sep 2020 06:47:56
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:29
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:30
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:40:32
User entered empty.	Megan Loughran (b) (4)	01 Sep 2020 06:47:56
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:13
User entered 'UN UNK 2000'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:40:41
User entered '0'	Megan Loughran (b) (4)	01 Sep 2020 06:47:56
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:17
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:43
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:19
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 06:47:56

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 22:40:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 22:40:10
Data point term sent to Coder	System	19 Jan 2021 19:45:18
Coding entries removed.	Benjamin Hull (b) (4)	19 Jan 2021 19:44:47
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:19:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:57:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:57:38
Data point term sent to Coder	System	01 Sep 2020 06:50:11
User entered 'Calcium with vitamin D supplement'	Megan Loughran (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).		20 Jan 2021 03:44:49
Query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Benjamin Hull (b) (4)	19 Jan 2021 19:44:50
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:44:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Benjamin Hull (b) (4)	19 Jan 2021 19:44:38
User opened query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:38:05
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:19:26
User entered 'No (N)'	Megan Loughran (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:44:47
User entered 'supplement' reason for change: Data Entry Error	(b) (4) Benjamin Hull (b) (4)	19 Jan 2021 19:44:47
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:19:28
User entered 'general health'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:30
User entered '1200/1600'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:34
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Sep 2020 06:49:41
User entered 'Other (OTHER)' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:41
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	01 Sep 2020 06:49:13
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:36
User entered 'MG/IU FOR CALCIUM + D' reason for change: Data Entry Error	Megan Loughran (b) (4)	01 Sep 2020 06:49:41
User entered 'dose is mg/IU for calcium + D'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:38
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:52
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:54
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:55
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:40
User entered 'UN UNK 2010'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:40:57
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:12
DataPoint Un-verified.	Megan Loughran (b) (4)	03 Nov 2020 19:03:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Megan Loughran (b) (4)	03 Nov 2020 19:03:41
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:19:43
User entered 'Yes (Y)'	Megan Loughran (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:14
User entered '10 Oct 2020' reason for change: Data Entry Error	Megan Loughran (b) (4)	03 Nov 2020 19:03:41
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:44
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User entered '1'	System	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User entered '1'	System	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:21
User entered '804 (804)'	System	01 Sep 2020 06:49:13

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Jan 2021 19:46:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 19:46:09
Data point term sent to Coder	System	19 Jan 2021 19:45:18
Coding entries removed.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:51:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:51:42
Data point term sent to Coder	System	01 Sep 2020 06:51:12
User entered 'vitamin d3'	Megan Loughran (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:04
	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:19:50
User entered 'No (N)'	(b) (4)	
	Megan Loughran (b) (4)	01 Sep 2020 06:50:20
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:04
User entered 'supplement' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:04
	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:19:51
User entered 'general health'	(b) (4)	
	Megan Loughran (b) (4)	01 Sep 2020 06:50:20
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:54
User entered '2000'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:55
User entered 'IU (IU)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:19
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:19:57
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:49
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:51
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:53
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:00
User entered 'UN UNK 2010'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:54
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:03
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:43:56
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:04
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 06:50:20

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Jan 2021 19:47:09
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Jan 2021 19:47:09
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	19 Jan 2021 19:46:20
Coding entries removed.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:38:43
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Sep 2020 15:38:43
User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 06:51:14
User entered 'glucosamine sulfate'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:27
	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:20:14
User entered 'No (N)'	(b) (4)	
	Megan Loughran (b) (4)	01 Sep 2020 06:51:09
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:27
User entered 'supplement' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:27
	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:20:17
User entered 'general health'	(b) (4)	
	Megan Loughran (b) (4)	01 Sep 2020 06:51:09
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:20
User entered '3000'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:22
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:04
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:25
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:07
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:08
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:10
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:20:28
User entered 'UN UNK 2005'	Megan Loughran (b) (4)	01 Sep 2020 06:51:09
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:44:13
User entered '0'	Megan Loughran (b) (4)	01 Sep 2020 06:51:09
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:29
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:19
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:31
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 06:51:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: PALMIDROL, PRODUCTSYNONYM: PALMITOYLETHANOLAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 15:08:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 15:08:17
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 16:37:24
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	18 Dec 2020 16:36:37
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'added' (Site from System).	Megan Loughran (b) (4)	18 Dec 2020 16:36:37
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 16:36:22
DataPoint Un-verified.	Megan Loughran (b) (4)	18 Dec 2020 16:36:16
	(b) (4)	
User entered 'CANABREX (palmitic acid mono-ethanolamide)' reason for change: Per Query Resolution	Megan Loughran (b) (4)	18 Dec 2020 16:36:16
	(b) (4)	
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 14:29:09
	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 18:53:02
Coding entries removed.	Megan Loughran (b) (4)	03 Nov 2020 18:52:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:20:37

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:00:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:00:50
Data point term sent to Coder	System	01 Sep 2020 06:52:14
User entered 'canabrex'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:40
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:44:42
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match' (Site from DM).		04 Nov 2020 06:29:56
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match' answered with 'added' (Site from DM).	Megan Loughran (b) (4)	03 Nov 2020 18:52:58
DataPoint Un-verified.	(b) (4)	
	Megan Loughran (b) (4)	03 Nov 2020 18:52:54
User entered 'osteoARTHRITIS' reason for change:	Megan Loughran (b) (4)	03 Nov 2020 18:52:54
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:20:43
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match' (Site from DM).		22 Oct 2020 06:53:53
User entered 'arthritis'	Megan Loughran (b) (4)	01 Sep 2020 06:52:06
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.		
	Megan Loughran (b) (4)	18 Dec 2020 16:36:16
	(b) (4)	
User entered '300' reason for change: New Information	Megan Loughran (b) (4)	18 Dec 2020 16:36:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:20:46
User entered '1'	Megan Loughran (b) (4)	01 Sep 2020 06:52:06
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Megan Loughran (b) (4)	18 Dec 2020 16:36:16
User entered 'mg (mg)' reason for change: New Information	(b) (4) Megan Loughran (b) (4)	18 Dec 2020 16:36:16
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:20:47
User entered 'tablet (TABLET)'	Megan Loughran (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:44
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:49
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:48
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:51
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:44:53
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:20:52
User entered 'UN UNK 2019'	Megan Loughran (b) (4)	01 Sep 2020 06:52:06
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:44:55
User entered '0'	Megan Loughran (b) (4)	01 Sep 2020 06:52:06
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:54
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:01
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:20:55
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 06:52:06

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Jan 2021 19:47:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Jan 2021 19:47:09
Data point term sent to Coder	System	19 Jan 2021 19:46:19
Coding entries removed.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:21:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:53:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 06:53:45
Data point term sent to Coder	System	01 Sep 2020 06:53:14
User entered 'multivitamin'	Megan Loughran (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:40
	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:21:23
User entered 'No (N)'	(b) (4)	
	Megan Loughran (b) (4)	01 Sep 2020 06:52:48
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Benjamin Hull (b) (4) (b) (4)	19 Jan 2021 19:45:40
User entered 'supplement' reason for change: Data Entry Error	Benjamin Hull (b) (4) (b) (4)	19 Jan 2021 19:45:40
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:21:26
User entered 'general health'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:21:28
User entered '2'	Megan Loughran (b) (4)	01 Sep 2020 06:52:48
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:21:30
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:21:32
User entered 'gummy bears'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:21:33
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:14
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:16
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:18
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:21:36
User entered 'UN UNK 2005'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:27
User entered '0'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 22:21:38
User entered 'Yes (Y)'	Megan Loughran (b) (4)	01 Sep 2020 06:52:48
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:31
User entered empty.	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:21:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 06:52:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	22 Feb 2021 17:47:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	22 Feb 2021 17:47:01
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	22 Feb 2021 17:46:43 22 Feb 2021 17:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:22:19
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)	28 Sep 2020 16:50:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	28 Sep 2020 16:50:46
Data point term sent to Coder User entered 'celebrex'	System Son Do (b) (4)	28 Sep 2020 16:49:51 28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:22:20
User entered 'No (N)'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		23 Feb 2021 09:17:36
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED: OSTEOARTHRITIS ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 17:46:46
DataPoint Un-verified.	(b) (4) Colleen McLellan (b) (4)	22 Feb 2021 17:46:36
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 17:46:36
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:42:00
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:22:23
User entered 'arthritis'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 19:16:01
User closed query 'Per source dose is documented as '100-200'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 19:15:59
Query 'Per source dose is documented as '100-200'. Please reconcile. ' answered with 'source and edc reconciled' (Site from CRA).	Megan Loughran (b) (4)	18 Dec 2020 16:38:24
User entered '200' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per source dose is documented as '100-200'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:47:10
DataPoint Un-verified.		06 Nov 2020 20:46:36
DataPoint Verified.		23 Oct 2020 22:22:25
User entered '100'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:22:27
User entered 'mg (mg)'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:39
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:22:30
User entered 'once daily (QD)'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:41
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:45:43
User entered 'Oral (ORAL)'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:46:19
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:46:21
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:46:22
User entered 'l'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Son Do (b) (4)	19 Jan 2021 17:35:34
User entered 'No (N)' reason for change: Data Entry Error	Son Do (b) (4)	19 Jan 2021 17:35:34
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:22:33
User entered 'Yes (Y)'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
DataPoint Un-verified.	Son Do (b) (4)	19 Jan 2021 17:35:34
User entered '12 Oct 2020' reason for change: Data Entry Error	Son Do (b) (4)	19 Jan 2021 17:35:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:46:25
User entered empty.	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:22:37
User entered 'No (N)'	Son Do (b) (4)	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User entered '1'	System	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User entered '1'	System	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:15
User entered '804 (804)'	System	28 Sep 2020 16:49:40

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:47:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 19:06:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 19:06:25
	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 19:05:22
User entered 'calcium w/ vitamin d'	Megan Loughran (b) (4)	03 Nov 2020 19:04:23
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 03:44:22
Query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Benjamin Hull (b) (4)	19 Jan 2021 19:45:55
DataPoint Un-verified.	Benjamin Hull (b) (4)	19 Jan 2021 19:45:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 19:45:52
User opened query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	Benjamin Hull (b) (4)	19 Jan 2021 19:45:52
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 11:36:52
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 20:47:39
	Megan Loughran (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered 'supplement'	Megan Loughran (b) (4)	03 Nov 2020 19:04:23
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered '600/800'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered 'mg/iu'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered 'once daily (QD)'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered empty.	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered empty.	Megan Loughran (b) (4)	03 Nov 2020 19:04:23
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered '10 Oct 2020'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered '0'	Megan Loughran (b) (4)	03 Nov 2020 19:04:23
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered empty.	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:47:39
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 19:04:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	18 Mar 2021 12:09:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:09:39
Data point term sent to Coder	System	16 Mar 2021 19:48:34
Data point term sent to Coder	System	16 Mar 2021 19:46:30
Coding entries removed.	Nancy Tang (b) (4)	16 Mar 2021 19:45:57
User signature succeeded.	(b) (4) Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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) (b) (4)	15 Dec 2020 00:00:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 00:00:57
Data point term sent to Coder	System	14 Dec 2020 20:01:37
User entered 'oxycodone'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:41:56
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:53:44
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:53:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'Conmed taken for OSTEOARTHRITIS LEFT HIP is listed in Med history. Please refer to medical history.' (Site from DM).	Nancy Tang (b) (4)	16 Mar 2021 19:47:54
User entered 'OSTEOARTHRITIS LEFT HIP' reason for change: Data Entry Error	Nancy Tang (b) (4)	16 Mar 2021 19:47:49
DataPoint Un-verified.	Nancy Tang (b) (4)	16 Mar 2021 19:45:57
Signature has been broken.	Nancy Tang (b) (4)	16 Mar 2021 19:45:57
User entered 'WORSENING OSTEOARTHRITIS LEFT HIP' reason for change: Data Entry Error	Nancy Tang (b) (4)	16 Mar 2021 19:45:57
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:32:27
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'hip pain'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '5' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:47:47
User entered '1'	(b) (4) Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	23 Feb 2021 09:23:34
' (Site from DM).		
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	Colleen McLellan (b) (4)	22 Feb 2021 17:47:57
' answered with 'UPDATED: PER (b) (6) 5MG DOSE '	(b) (4)	
(Site from DM).		
User entered 'mg (mg)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:47:47
	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	02 Feb 2021 12:45:25
' (Site from DM).		
User entered 'tablet (TABLET)'	Benjamin Hull (b) (4)	14 Dec 2020 20:01:09
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'as needed (PRN)'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Benjamin Hull (b) (4)	14 Dec 2020 20:01:09
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Benjamin Hull (b) (4) (b) (4)	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:01:09

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:17
Data point term sent to Coder	System	18 Dec 2020 16:40:25
User entered 'ondansetron hcl'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'nausea'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '4'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User entered '2'	System	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User entered '1'	System	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:38
User entered '804 (804)'	System	18 Dec 2020 16:39:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 07:34:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 07:34:09
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 17:51:50
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 17:51:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:34:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:34:29
Data point term sent to Coder	System	18 Dec 2020 16:41:26
User entered 'fentanyl citrate'	Megan Loughran (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		23 Feb 2021 09:26:02
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'LEFT FLANK PAIN - PER (b) (6) (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 17:51:37
User entered 'PAIN (LEFT FLANK)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:51:30
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:45:52
User entered 'pain'	Megan Loughran (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '50'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'ug (ug)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User entered empty.	System	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User entered empty.	System	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User entered empty.	System	18 Dec 2020 16:40:41

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 21:49:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 21:49:15
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:23
Data point term sent to Coder	System	18 Dec 2020 16:42:28
User entered 'SODIUM chloride'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'dehydration'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '1000'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User entered '2'	System	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User entered '1'	System	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:42
User entered '804 (804)'	System	18 Dec 2020 16:41:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:26:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:26:59
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 17:58:01
User entered 'IOHEXOL 350MG/ML' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:57:39
Data point term sent to Coder	System	22 Feb 2021 17:53:54
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 17:53:40
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:35:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:35:13
Data point term sent to Coder	System	18 Dec 2020 16:43:28
User entered 'iohexol'	Megan Loughran (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).		23 Feb 2021 14:34:08
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'CONTRAST FOR CHEST CT - SEE AE LOG LINE 1' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 17:53:55
User entered 'CONTRAST FOR CHEST CT (AE LOG LINE 1)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:53:40
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:46:18
User entered 'contrast for imaging'	Megan Loughran (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '35000' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:57:39
User entered '100'	(b) (4) Megan Loughran (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of just mL count, as there are multiple concentration options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		23 Feb 2021 11:19:43
Query 'Per DM CLR: Please provide the actual dose for this medication instead of just mL count, as there are multiple concentration options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'PER HOSPITAL DISCHARGE INFO - 350MG/ML CONCENTRATION AND 100ML GIVEN. THEREFORE 35,000MG GIVEN.' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 17:58:20
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 17:57:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of just mL count, as there are multiple concentration options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:46:29
User entered 'mL (mL)'	Megan Loughran (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User entered empty.	System	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User entered empty.	System	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:45
User entered empty.	System	18 Dec 2020 16:42:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	05 Mar 2021 05:15:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:15:46
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 17:59:04
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 17:58:48
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)	18 Dec 2020 17:35:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:35:14
Data point term sent to Coder	System	18 Dec 2020 16:44:29
User entered 'lidocaine 5% patch'	Megan Loughran (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		23 Feb 2021 09:22:00
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'LEFT FLANK PAIN ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 17:58:55
User entered 'PAIN LEFT FLANK' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:58:48
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:47:34
User entered 'pain'	Megan Loughran (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'l'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'patch'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Transdermal (TRANSDERMAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User entered empty.	System	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User entered empty.	System	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:56
User entered empty.	System	18 Dec 2020 16:43:51

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:29
Data point term sent to Coder	System	18 Dec 2020 16:44:29
User entered 'diazepam'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'muscle spasm'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '5'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User entered empty.	System	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User entered empty.	System	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:58
User entered empty.	System	18 Dec 2020 16:44:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 12:22:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	02 Mar 2021 12:22:43
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:00:05
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 17:59:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: KETOROLAC [KETOROLAC TROMETHAMINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:35:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	18 Dec 2020 17:35:14
Data point term sent to Coder	System	18 Dec 2020 16:45:30
User entered 'ketorolac tromethamine'	Megan Loughran (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		23 Feb 2021 09:22:27
User entered 'PAIN LEFT FLANK' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 17:59:29
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'LEFT FLANK PAIN ' (Site from DM).	(b) (4) Colleen McLellan (b) (4)	22 Feb 2021 17:59:22
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:49:29
User entered 'pain'	Megan Loughran (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '15'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User entered empty.	System	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User entered empty.	System	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:48
User entered empty.	System	18 Dec 2020 16:45:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:53:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:53:40
Data point term sent to Coder	System	18 Dec 2020 16:46:30
User entered 'phenergan'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'nausea'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12.5'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '31 Aug 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User entered empty.	System	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User entered empty.	System	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:20
User entered empty.	System	18 Dec 2020 16:46:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:45:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:45:07
Data point term sent to Coder	System	22 Feb 2021 18:01:07
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:00:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:33
Data point term sent to Coder	System	18 Dec 2020 16:47:31
User entered 'hydrocodone-acetaminophen'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		23 Feb 2021 09:22:49
User entered 'PAIN LEFT FLANK' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:00:23
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'LEFT FLANK PAIN' (Site from DM).	(b) (4) Colleen McLellan (b) (4)	22 Feb 2021 18:00:16
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:49:52
User entered 'pain'	Megan Loughran (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '5/325'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '01 Sep 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '01 Sep 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User entered empty.	System	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User entered empty.	System	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:09
User entered empty.	System	18 Dec 2020 16:46:47

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	26 Feb 2021 07:43:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 07:43:08
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:01:20
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 18:00:47
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)	18 Dec 2020 17:34:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:34:33
Data point term sent to Coder	System	18 Dec 2020 16:47:31
User entered 'gabapentin'	Megan Loughran (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		23 Feb 2021 09:16:12
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'LEFT FLANK PAIN' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:00:54
User entered 'PAIN LEFT FLANK' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:00:47
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:50:14
User entered 'pain'	Megan Loughran (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '300'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '01 Sep 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '01 Sep 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User entered empty.	System	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User entered empty.	System	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:11
User entered empty.	System	18 Dec 2020 16:47:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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)	18 Dec 2020 17:34:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:45
Data point term sent to Coder	System	18 Dec 2020 16:52:34
User entered 'acetaminophen'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'osteoarthritis'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '500'	Megan Loughran (b) (4)	18 Dec 2020 16:51:38
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 16:51:38
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'as needed (PRN)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 16:51:38
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'I'	Megan Loughran (b) (4)	18 Dec 2020 16:51:38
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 16:51:38
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:51:38

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: FOSAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:49
Data point term sent to Coder	System	18 Dec 2020 16:55:37
User entered 'fosamax'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'osteopenia'	Megan Loughran (b) (4)	18 Dec 2020 16:55:25
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '70'	Megan Loughran (b) (4)	18 Dec 2020 16:55:25
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'every week (QS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 16:55:25
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '03 Sep 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 16:55:25
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	18 Dec 2020 16:55:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:14
Data point term sent to Coder	System	18 Dec 2020 17:04:42
User entered 'flu vaccine'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'prophylaxis for flu'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0.5'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '10 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '10 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User entered empty.	System	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User entered empty.	System	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:07
User entered empty.	System	18 Dec 2020 17:03:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 07:33:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:09:03
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 18:08:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:43:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:43:48
Data point term sent to Coder	System	18 Dec 2020 17:43:10
User entered 'fentanyl'	Megan Loughran (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:21:51
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS MEDICATION WAS GIVEN FOR ANESTHESIA FOR CON PROCEDURE LISTED ABOVE. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:09:50
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:08:34
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:59:08
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '100'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'ug (ug)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User entered empty.	System	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User entered empty.	System	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:09
User entered empty.	System	18 Dec 2020 17:42:16

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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) (b) (4)	25 Feb 2021 06:47:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:47:11
Data point term sent to Coder	System	22 Feb 2021 18:11:06
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:10:44
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) (b) (4)	18 Dec 2020 17:44:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:44:47
Data point term sent to Coder	System	18 Dec 2020 17:43:10
User entered 'hydromorphone'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:22:27
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. MEDICATION WAS GIVEN WITH ANESTHESIA FOR CON PROCEDURE LISTED ABOVE. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:11:07
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:10:44
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:59:21
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'l'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User entered empty.	System	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User entered empty.	System	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:53
User entered empty.	System	18 Dec 2020 17:42:53

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	05 Mar 2021 05:14:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:14:47
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:12:07
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 18:11:22
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)	18 Dec 2020 17:45:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:45:50
Data point term sent to Coder	System	18 Dec 2020 17:44:10
User entered 'lidocaine 2%'	Megan Loughran (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:22:44
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:11:53
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:59:40
User entered 'anesthesia'	Megan Loughran (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '50'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User entered empty.	System	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User entered empty.	System	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:11
User entered empty.	System	18 Dec 2020 17:43:23

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	05 Mar 2021 05:33:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:33:47
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:13:08
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 18:12:10
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)	18 Dec 2020 18:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:51:48
Data point term sent to Coder	System	18 Dec 2020 17:44:10
User entered 'propofol'	Megan Loughran (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:22:53
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:12:10
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:12:00
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:59:54
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '160'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User entered empty.	System	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User entered empty.	System	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:13
User entered empty.	System	18 Dec 2020 17:43:55

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
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) (b) (4)	25 Mar 2021 10:15:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 10:15:24
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:13:08 22 Feb 2021 18:12:21
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) (b) (4)	18 Dec 2020 18:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:51:48
Data point term sent to Coder User entered 'reoronium'	System Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:11 18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:23:02
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:12:28
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:00:08
User entered 'anesthesia'	Megan Loughran (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '50'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User entered empty.	System	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User entered empty.	System	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:13
User entered empty.	System	18 Dec 2020 17:44:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:28:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:28:00
Data point term sent to Coder	System	22 Feb 2021 18:15:10
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:14:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:46:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:46:39
Data point term sent to Coder	System	18 Dec 2020 17:45:13
User entered 'cefazolin'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:14:40
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:23:15
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN prophylactically for intra-op infection FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:15:11
User entered 'intra-op infection prophylaxis' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:14:40
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:00:23
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '2'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'g (g)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:51:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 17:51:43
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 17:51:43
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:45:02
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User entered empty.	System	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User entered empty.	System	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:43
User entered empty.	System	18 Dec 2020 17:45:02

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:20:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:20:03
Data point term sent to Coder	System	22 Feb 2021 18:16:11
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:15:41
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:49:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:49:39
Data point term sent to Coder	System	18 Dec 2020 17:47:14
User entered 'dexamethasone'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:23:41
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:15:41
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:15:30
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:00:35
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '10'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User entered empty.	System	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User entered empty.	System	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:44
User entered empty.	System	18 Dec 2020 17:46:49

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:05:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:05:01
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:16:10
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:15:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:55:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:55:40
Data point term sent to Coder	System	18 Dec 2020 17:48:14
User entered 'ondansetron'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:24:05
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:16:03
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:15:58
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:00:49
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '4'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User entered empty.	System	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User entered empty.	System	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:46
User entered empty.	System	18 Dec 2020 17:47:24

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
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) (b) (4)	19 Mar 2021 11:37:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:37:31
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:17:11
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:16:42
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) (b) (4)	18 Dec 2020 18:52:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:52:58
Data point term sent to Coder	System	18 Dec 2020 17:48:14
User entered 'phenylephrine'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:24:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:16:50
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:16:42
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:01:35
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '400'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'ug (ug)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User entered empty.	System	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User entered empty.	System	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:48
User entered empty.	System	18 Dec 2020 17:48:05

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	04 Mar 2021 23:51:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 23:51:52
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:18:14
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 18:17:45
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)	18 Dec 2020 18:49:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:49:48
Data point term sent to Coder	System	18 Dec 2020 17:49:18
User entered 'sugammadex'	Megan Loughran (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:24:22
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:17:49
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:06:57
User entered 'anesthesia'	Megan Loughran (b) (4)	18 Dec 2020 17:48:34
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '200'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User entered empty.	System	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User entered empty.	System	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User entered empty.	System	18 Dec 2020 17:48:34

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 14:23:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 14:23:03
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:19:15
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 18:18:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 02:17:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 02:17:47
Data point term sent to Coder	System	18 Dec 2020 17:50:19
User entered 'tranexamic acid'	Megan Loughran (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:24:28
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:18:18
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:18:07
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:07:17
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '1000'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User entered empty.	System	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User entered empty.	System	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:53
User entered empty.	System	18 Dec 2020 17:49:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
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)	05 Mar 2021 05:33:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 05:33:47
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:02:05
Data point term sent to Coder	System	22 Feb 2021 18:19:15
Coding entries removed.	Colleen McLellan (b) (4)	22 Feb 2021 18:18:43
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)	18 Dec 2020 18:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:51:48
Data point term sent to Coder	System	18 Dec 2020 17:50:18
User entered 'propofol'	Megan Loughran (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:24:36
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:18:47
User entered 'TOTAL LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:18:43
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:07:37
User entered 'anesthesia'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '66.12'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User entered empty.	System	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User entered empty.	System	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:54
User entered empty.	System	18 Dec 2020 17:49:52

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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)	22 Feb 2021 18:21:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:21:01
Data point term sent to Coder	System	22 Feb 2021 18:20:16
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 18:19:42
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)	18 Dec 2020 17:52:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:52:40
Data point term sent to Coder	System	18 Dec 2020 17:51:19
User entered 'lactated ringers'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		23 Feb 2021 11:24:54
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'AE LOG LINE 4, CP LOG LINE 5. THIS WAS GIVEN AS ANESTHESIA FOR CON PROCEDURE LISTED. ' (Site from DM).	Colleen McLellan (b) (4)	22 Feb 2021 18:19:47
User entered 'LEFT TOTAL HIP REPLACEMENT' reason for change: Data Entry Error	Colleen McLellan (b) (4)	22 Feb 2021 18:19:42
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:08:06
User entered 'anesthesia'	Megan Loughran (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '1000'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mL (mL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User entered empty.	System	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User entered empty.	System	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:56
User entered empty.	System	18 Dec 2020 17:50:22

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL RAPID RELEASE GELS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:59:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:59:40
Data point term sent to Coder	System	18 Dec 2020 17:56:23
User entered 'acetaminophen rapid release gelcap'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'hip surgery - pain'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '1000'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User entered empty.	System	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User entered empty.	System	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:59
User entered empty.	System	18 Dec 2020 17:56:17

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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)	18 Dec 2020 17:58:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:58:42
Data point term sent to Coder	System	18 Dec 2020 17:57:25
User entered 'acetaminophen'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'hip surgery, pain'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '1000'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '13 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User entered '2'	System	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User entered '1'	System	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:02
User entered '804 (804)'	System	18 Dec 2020 17:57:03

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:00:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:00:42
Data point term sent to Coder	System	18 Dec 2020 17:58:26
User entered 'decadron'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'hip surgery'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '4'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User entered empty.	System	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User entered empty.	System	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:13
User entered empty.	System	18 Dec 2020 17:58:11

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:01:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:01:40
Data point term sent to Coder	System	18 Dec 2020 17:59:27
User entered 'famotidine'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'hip surgery'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '20'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User entered '2'	System	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User entered '1'	System	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:15
User entered '804 (804)'	System	18 Dec 2020 17:58:48

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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)	18 Dec 2020 18:00:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:00:43
Data point term sent to Coder	System	18 Dec 2020 18:00:28
User entered 'senokot-s'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'prophylaxis for stool softening during opiod use'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '17.2/100'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User entered '2'	System	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User entered '1'	System	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:28
User entered '804 (804)'	System	18 Dec 2020 18:00:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% & DEXTROSE 5% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:04:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:04:39
Data point term sent to Coder	System	18 Dec 2020 18:02:29
User entered 'dextrose 5% sodium chloride 0.9% infusion'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'hip surgery'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '75'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'ml/hr'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'other (OTHER)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'continuous'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '13 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User entered empty.	System	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User entered empty.	System	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:31
User entered empty.	System	18 Dec 2020 18:02:25

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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) (b) (4)	18 Dec 2020 18:12:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:12:41
Data point term sent to Coder	System	18 Dec 2020 18:10:43
Data point term sent to Coder	System	18 Dec 2020 18:09:42
User entered 'hydromorphone'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'HIP SURGERY, pain' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 18:09:55
User entered 'hip surgery'	(b) (4) Megan Loughran (b) (4)	18 Dec 2020 18:08:44
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '.25'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User entered '2'	System	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User entered '1'	System	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User entered '804 (804)'	System	18 Dec 2020 18:08:44

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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) (b) (4)	18 Dec 2020 18:12:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:12:41
Data point term sent to Coder	System	18 Dec 2020 18:10:44
Data point term sent to Coder	System	18 Dec 2020 18:09:41
User entered 'hydromorphone'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'HIP SURGERY, PAIN' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 18:10:07
User entered 'hip surgery pain'	(b) (4) Megan Loughran (b) (4)	18 Dec 2020 18:09:28
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0.5'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intravenous (INTRAVENOUS)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User entered '2'	System	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User entered '1'	System	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:18
User entered '804 (804)'	System	18 Dec 2020 18:09:28

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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) (b) (4)	18 Dec 2020 18:55:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:55:37
Data point term sent to Coder	System	18 Dec 2020 18:12:45
User entered 'oxycodone'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'post operative pain, hip'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '5'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 18:12:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 18:12:40
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Megan Loughran (b) (4)	18 Dec 2020 18:12:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Dec 2020 18:12:01
	Megan Loughran (b) (4)	18 Dec 2020 18:12:01
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '13 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '13 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User entered '2'	System	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User entered '1'	System	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:36
User entered '804 (804)'	System	18 Dec 2020 18:12:01

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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) (b) (4)	18 Dec 2020 18:55:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:55:05
Data point term sent to Coder	System	18 Dec 2020 18:13:47
User entered 'oxycodone'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'post operative pain, hip'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '5'	Megan Loughran (b) (4)	18 Dec 2020 18:13:32
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 18:13:32
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'other (OTHER)'	Megan Loughran (b) (4)	18 Dec 2020 18:13:32
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'every 6 hours as needed'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4)	18 Dec 2020 18:13:32
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 18:13:32
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 18:13:32

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
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)	18 Dec 2020 18:16:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:16:31
Data point term sent to Coder	System	18 Dec 2020 18:14:48
User entered 'senokot-s'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'prophylaxis for constipation d/t opioid prescription'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '17.2/100'	Megan Loughran (b) (4)	18 Dec 2020 18:14:45
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 18:14:45
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'twice daily (BID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4)	18 Dec 2020 18:14:45
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4)	18 Dec 2020 18:14:45
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 18:14:45
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 18:14:45
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Dec 2020 18:14:45

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:19:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:19:44
Data point term sent to Coder	System	18 Dec 2020 18:16:51
User entered 'decadron'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'post operative pain, hip'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '4'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '13 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '13 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User entered empty.	System	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User entered empty.	System	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:42
User entered empty.	System	18 Dec 2020 18:15:59

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:19:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:19:44
Data point term sent to Coder	System	18 Dec 2020 18:16:49
User entered 'decadron'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'post operative pain, hip'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '2'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '14 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '14 Oct 2020'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User entered empty.	System	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User entered empty.	System	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:51
User entered empty.	System	18 Dec 2020 18:16:33

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
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)	18 Dec 2020 18:18:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:18:41
Data point term sent to Coder	System	18 Dec 2020 18:17:52
User entered 'acetaminophen'	Megan Loughran (b) (4)	18 Dec 2020 18:17:21
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'post operative pain, hip'	Megan Loughran (b) (4)	18 Dec 2020 18:17:21
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '1000'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mg (mg)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'four times daily (QID)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Oral (ORAL)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '12 Oct 2020'	Megan Loughran (b) (4)	18 Dec 2020 18:17:21
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Megan Loughran (b) (4)	18 Dec 2020 18:17:21
	(b) (4)	

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Dec 2020 18:17:21

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:48:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:48:10
Data point term sent to Coder	System	19 Jan 2021 19:47:21
Coding entries removed.	Benjamin Hull (b) (4) (b) (4)	19 Jan 2021 19:46:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 17:36:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 17:36:10
Data point term sent to Coder	System	19 Jan 2021 17:34:36
User entered 'flu vaccine'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Yes (Y)'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'prophylaxis for flu' reason for change:	Benjamin Hull (b) (4)	19 Jan 2021 19:46:40
Data Entry Error	(b) (4)	
User entered 'flu'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0.5'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'mL (mL)'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'once (ONCE)'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered empty.	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '10 Oct 2020'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '0'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered '10 Oct 2020'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:02:05
User entered 'No (N)'	Son Do (b) (4)	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User entered empty.	System	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User entered empty.	System	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:11:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:25
User entered empty.	System	19 Jan 2021 17:34:26

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:11:03

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:46:40
User closed query 'Per source subject had hip surgery. Please add record. ' (Site from CRA).		21 Jan 2021 20:46:38
Query 'Per source subject had hip surgery. Please add record. ' answered with 'added' (Site from CRA).	Megan Loughran (b) (4)	18 Dec 2020 16:18:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	18 Dec 2020 16:18:28
User opened query 'Per source subject had hip surgery. Please add record. ' (Site from CRA).	Megan Loughran (b) (4)	06 Nov 2020 20:51:31
User entered 'No (N)'	(b) (4)	01 Sep 2020 06:53:00

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered '31 Aug 2020'	Megan Loughran (b) (4)	18 Dec 2020 16:19:57

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'cta chest'	Megan Loughran (b) (4)	18 Dec 2020 16:19:57

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'Diagnostic (DIAGNOSTIC)'	Megan Loughran (b) (4)	18 Dec 2020 16:19:57

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:03

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered empty.	Megan Loughran (b) (4)	18 Dec 2020 16:19:57

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:24
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered '31 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:22

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:24
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'cta abdomen and pelvis'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:22

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:24
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:22

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:11:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:24
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:22

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:03

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:27
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered '31 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:43

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:27
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'ekg'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:43

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:27
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:43

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:11:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:27
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:20:43

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:03

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:31
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered '31 Aug 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:21:03

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:31
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'chest xray'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:21:03

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:31
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:21:03

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:11:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:31
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered empty.	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 16:21:03

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:35
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered '12 Oct 2020'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:18:32

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:35
DataPoint Verified.		07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
User entered 'total hip replacement, left'	(b) (4) Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:18:32

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:35
DataPoint Verified.	(b) (4)	07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	22 Feb 2021 17:46:00
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	22 Feb 2021 17:45:49
Signature has been broken.	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 17:45:49
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	22 Feb 2021 17:45:49
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:25:45
User entered 'Other (OTHER)'	Megan Loughran (b) (4) (b) (4)	18 Dec 2020 18:18:32

US3642035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:11:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:19:35
DataPoint Verified.	(b) (4)	07 Apr 2021 19:42:12
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	Colleen McLellan (b) (4)	22 Feb 2021 17:46:00
Signature has been broken.	(b) (4)	
	Colleen McLellan (b) (4)	22 Feb 2021 17:45:49
	(b) (4)	
User entered 'OSTEOARTHRITIS LEFT HIP'	Colleen McLellan (b) (4)	22 Feb 2021 17:45:49
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:25:45
	(b) (4)	
User entered 'scheduled surgical procedure'	Megan Loughran (b) (4)	18 Dec 2020 18:18:32
	(b) (4)	

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'USA-US109-2020-MRNA-1273-P301000008'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Stephen'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Spector'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'US'	(b) (4) System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 18:46:15
Signature has been broken.	System	22 Feb 2021 21:29:47
User entered '2'	System	22 Feb 2021 21:29:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
User entered '1'	System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'USA-US109-2020-MRNA-1273-P301000008'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Stephen'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Spector'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'US'	(b) (4) System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 18:46:15
Signature has been broken.	System	22 Feb 2021 21:29:47
User entered '2'	System	22 Feb 2021 21:29:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
User entered '1'	System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:11:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered '21/Dec/2020 09:40'	(b) (4) System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:11:03

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)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'USA-US109-2020-MRNA-1273-P301000008'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Stephen'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Spector'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'US'	(b) (4) System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 18:46:15
Signature has been broken.	System	22 Feb 2021 21:29:47
User entered '2'	System	22 Feb 2021 21:29:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
User entered '1'	System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:11:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered '22/Feb/2021 16:29'	(b) (4) System	22 Feb 2021 21:29:47

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:11:03

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)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:38:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:29:47

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'USA-US109-2020-MRNA-1273-P301000008'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Yes (Y)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'No (N)'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Stephen'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:40:28
User entered 'Spector'	System	21 Dec 2020 15:35:13

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:34:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
User entered 'US'	(b) (4) System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Mar 2021 18:46:15
Signature has been broken.	System	22 Feb 2021 21:29:47
User entered '2'	System	22 Feb 2021 21:29:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:26:07
	(b) (4)	
User entered '1'	System	21 Dec 2020 15:40:40

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:11:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:42:23
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
User entered '26/Mar/2021 11:46'	(b) (4) System	26 Mar 2021 18:46:15

US3642035

Folder: SAE USA-US109-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:11:03

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)	07 Apr 2021 19:42:23
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:15:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:46:15