

US3422135 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:33:17

All time stamps listed in this document are displayed in GMT

US3422135

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

[Participant ID](#)

US3422135

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

US3422135

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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 type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 20:12:10

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
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 20:12:10

Generated On: 09 Jun 2021 17:33:17

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
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 20:12:10

Generated On: 09 Jun 2021 17:33:17

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3422135

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
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 20:12:10

Generated On: 09 Jun 2021 17:33:17

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Condition	ALLERGY ALPHA-GEL
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3422135

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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>)	08:41 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 08:41
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	200 lb
BMI (<i>xxx.x</i>)	32.34834 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) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:12:10

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

BABYSIT 6 GRANDCHILDREN,
FREQUENT VISITS TO STORES
WEEKLY, WEEKLY GOLF TEAM

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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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:12:10

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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) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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

What was the participant's randomization number? 188199

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) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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)	08:41 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 08:41
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 09:52
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	057 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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) 09:22 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 09:22

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) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

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)	08:47 (24 HR)
Collection date and time (derived)	28 AUG 2020 08:47

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Collection date (<i>dd MMM yyyy</i>)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:45	28 AUG 2020 08:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

97.3 °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

28 AUG 2020 09:58

PC Open Date & Time

28 AUG 2020 09:42

PC Close Date & Time

28 AUG 2020 12:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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 97.8 °F

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

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

PC Time Stamp	29 AUG 2020 00:37
PC Open Date & Time	28 AUG 2020 13:07
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

30 AUG 2020 10:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

98.3 °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

31 AUG 2020 07:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

98.3 °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

01 SEP 2020 10:21

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

98.3 °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

02 SEP 2020 11:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

98.0 °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

03 SEP 2020 10:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 10:28

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 10:00

PC Open Date & Time

28 AUG 2020 09:42

PC Close Date & Time

28 AUG 2020 12:12

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

29 AUG 2020 00:38

PC Open Date & Time

28 AUG 2020 13:07

PC Close Date & Time

29 AUG 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

30 AUG 2020 10:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

31 AUG 2020 07:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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 10:21

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

02 SEP 2020 11:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

03 SEP 2020 10:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

04 SEP 2020 10:28

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 10:01
PC Open Date & Time	28 AUG 2020 09:42
PC Close Date & Time	28 AUG 2020 12:12

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 00:39
PC Open Date & Time	28 AUG 2020 13:07
PC Close Date & Time	29 AUG 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

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 ☒

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 10:15
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

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)

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 07:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

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 ☒

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 10:22
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2589

EAB) (1725)

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

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EAB) (1725)

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 10:24
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

59 of 2589

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 10:29
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3422135

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:12:11

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:15:18

Generated On: 09 Jun 2021 17:33:17

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)	08:10 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 08:10
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	079 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:15:18

Generated On: 09 Jun 2021 17:33:17

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)	09:20 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:20
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	068 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 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

US3422135

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:12:11

Generated On: 09 Jun 2021 17:33:17

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.

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:12:11

Generated On: 09 Jun 2021 17:33:17

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) 08:50 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 08:50

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

US3422135

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:12:11

Generated On: 09 Jun 2021 17:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

08:13 (24 HR)

Collection date and time (derived)

25 SEP 2020 08:13

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:12:11

Generated On: 09 Jun 2021 17:33:17

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	08:15	25 SEP 2020 08:15
Nasopharyngeal Swab 2	No		

US3422135

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:11

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

98.5 °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

25 SEP 2020 09:22

PC Open Date & Time

25 SEP 2020 09:10

PC Close Date & Time

25 SEP 2020 11:40

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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 99.0 °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	26 SEP 2020 11:11
PC Open Date & Time	25 SEP 2020 12:35
PC Close Date & Time	26 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

100.1 °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

27 SEP 2020 09:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 SEP 2020 11:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

98.7 °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

29 SEP 2020 07:48

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

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

30 SEP 2020 11:07

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

99.2 °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 08:19

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 09:36

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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 09:22

PC Open Date & Time

25 SEP 2020 09:10

PC Close Date & Time

25 SEP 2020 11:40

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

26 SEP 2020 11:12

PC Open Date & Time

25 SEP 2020 12:35

PC Close Date & Time

26 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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)**

40

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

27 SEP 2020 09:03

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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)**

40

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

28 SEP 2020 11:09

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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)**

30

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

29 SEP 2020 07:49

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

30 SEP 2020 11:07

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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 08:19

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 09:36

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 09:23
PC Open Date & Time	25 SEP 2020 09:10
PC Close Date & Time	25 SEP 2020 11:40

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 11:13
PC Open Date & Time	25 SEP 2020 12:35
PC Close Date & Time	26 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

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 ☒

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 09:04
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

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)

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 11:10
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

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 ☒

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 07:50
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 11:08
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

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 ☒

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 08:20
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

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 ☒

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 09:36
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3422135

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:12:10

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:15:19

Generated On: 09 Jun 2021 17:33:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:15:19

Generated On: 09 Jun 2021 17:33:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:15
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	090 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	074 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3422135

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:15:19

Generated On: 09 Jun 2021 17:33:17

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.

US3422135

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:15:19

Generated On: 09 Jun 2021 17:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

23 OCT 2020 08:20

US3422135

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:15:19

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 12:32:02

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

04 NOV 2020 00:02:13

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 20:33:22
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 12:09:47
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 12:53:37

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 10:57:33

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 12:01:10

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 11:18:21
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 13:09:14

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 10:58:22

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 16:27:28

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

28 JAN 2021 14:34:46

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 00:01:55

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 00:01:37

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 12:19:41

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 11:34:52

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

28 FEB 2021 13:56:55

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 09:56:03
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

17 MAR 2021 12:00:24

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

23 MAR 2021 12:01:19

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

30 MAR 2021 13:46:21

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 08:20:18
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 <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 APR 2021 07:55:04
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 07:07:17

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 10:34:43

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 00:01:33
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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="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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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="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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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°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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	23 DEC 2021 23:59
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US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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="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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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="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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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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US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	27 OCT 2022 23:59
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US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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"/>

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:33:17

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 13:57:07

US3422135

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:50:09

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:50:09

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

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

Visit date (dd MMM yyyy)	30 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

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) _____

US3422135

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

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.

US3422135

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 MAR 2021
Collection time (<i>00:00-23:59</i>)	11:15 (24 HR)
Collection date and time (derived)	30 MAR 2021 11:15

US3422135

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:36:45

Generated On: 09 Jun 2021 17:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3422135

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:36:45

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422135

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3422135

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:33:17

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3422135

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

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

Visit date (dd MMM yyyy)	11 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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US3422135

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 20:49:24

Generated On: 09 Jun 2021 17:33:17

Date of updated informed consent (*dd MMM yyyy*) 06 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 11 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3422135

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	12:18 (24 HR)
Collection date and time (derived)	11 JAN 2021 12:18

US3422135

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	12:15
Collection Date and Time (derived)	11 JAN 2021 12:15

US3422135

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Mar 2021 21:30:56

Generated On: 09 Jun 2021 17:33:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 21:30:56

Generated On: 09 Jun 2021 17:33:17

AEID	USA-US082-2020-MRNA-1273-P30 1000001
Adverse event	SPINAL STENOSIS
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)	06 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 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)	06 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	08 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 (1)

Data signed: (b) (4) 18 Mar 2021 21:30:56

Generated On: 09 Jun 2021 17:33:17

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	PATIENT WAS ADMITTED FOR PLANNED PROCEDURE (LUMBAR SPINE L4-L5 FUSION) DUE TO SCIATICA THAT STARTED AGO. INPATIENT FOR 48 HOURS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 21:30:56

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

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

Yes ☒

No ☐

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

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 125

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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 1984
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 1994
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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 2002	
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 (4)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication METOPROLOL ER

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 2003	
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"/>

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

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 (6)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 2007	
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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication GENERAL ANXIETY

Dose per administration 7.5

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 (7)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 01 Apr 2021 23:11:55

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 1979	
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 (9)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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Name of Medication	TRULICITY
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>

Indication	TYPE II DIABETES
Dose per administration	1.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 2016	
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 (10)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication SCIATICA

Dose per administration 220

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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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) _____		
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 (11)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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Name of Medication SINGULAR

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (11)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 01 Apr 2021 23:11:55

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Name of Medication VITAMIN D-3

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

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 (12)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify INHALED

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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (14)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE 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 (14)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		08 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)		20 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 (15)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication POST-OPERATIVE CARE PAIN
AND MUSCLE SPASM

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 (15)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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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)	06 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)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication MEDROL DOSE PACK

Prophylaxis Yes ☐
No ☒

Indication POST-OPERATIVE CARE, PAIN
AND INFLAMMATION

Dose per administration 1

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

If dose unit is Other, specify

PARTICIPANT TOOK
STANDARD MEDROL DOSE
PACK. 24 MG DAY 1, 20 MG DAY
2, 16 MG DAY 3, 12 MG DAY 4, 8
MG DAY 5, AND 4 MG DAY 6.

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 ☒

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Form: Prior/Concomitant Medication and Vaccination (16)

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)	08 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)	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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Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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Name of Medication MECLIZINE

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PREVENTION, POST
OPERATIVE CARE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (17)

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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)		06 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)		06 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 (18)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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Name of Medication POVIDONE IODINE TOPICAL

Prophylaxis Yes ☒
No ☐

Indication POST-OPERATIVE CARE,
SPINAL STENOSIS REPAIR

Dose per administration 1

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

If dose unit is Other, specify TOPICAL APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 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)		06 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 (19)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ACETAMINOPHEN-HYDROCOD
ONE (325/5 MG)

Prophylaxis Yes ☐
No ☒

Indication PAIN CONTROL, SPINAL
STENOSIS REPAIR

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 (19)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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)		06 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 (21)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication SURGICAL PROPHYLAXIS,
SPINAL STENOSIS REPAIR

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

TWICE

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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)		07 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 (22)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication GLYCOPYRROLATE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	6 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)		6 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 (23)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication NEOSTIGMINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	6 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)		6 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 (24)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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 (24)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	6 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)		6 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 (25)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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 (25)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	6 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)	6 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 (26)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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)		06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

Dose per administration 244.125

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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)	06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)	06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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 (29)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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)		06 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 (30)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)	06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication KETOROLAC

Prophylaxis Yes ☒
No ☐

Indication PAIN CONTROL, SPINAL
STENOSIS REPAIR

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)		06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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)		06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☒
No ☐

Indication PAIN PREVENTION

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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) 06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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 (34)

Data signed: (b) (4) 01 Apr 2021 23:11:55

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 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)		06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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)		06 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 (36)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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 (36)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)	06 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 (37)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

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 (37)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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)		06 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 (38)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)		06 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)		06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication BKK [BUPIVACAINE,
KETOROLAC AND KETAMINE]

Prophylaxis Yes ☐
No ☒

Indication SPINAL STENOSIS REPAIR

Dose per administration 55

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) 01 Apr 2021 23:11:55

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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)	06 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)		06 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) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ALBUMIN HUMAN

Prophylaxis Yes ☐
No ☒

Indication SURGICAL CARE, SPINAL
STENOSIS REPAIR

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)		06 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"/>

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ACETAMINOPHEN-HYDROCOD
ONE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN
CONTROL

Dose per administration 325/10

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	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)	06 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)		06 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"/>

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

Name of Medication ACETAMINOPHEN-HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN CONTROL

Dose per administration 325/7.5

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 01 Apr 2021 23:11:55

Generated On: 09 Jun 2021 17:33:17

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 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"/>

US3422135

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3422135

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
06 OCT 2020	LAMINECTOMY WITH POSTEROLATERAL FUSION	Medical History	

US3422135

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:33:17

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

US3422135

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:33:17

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

SAEID	USA-US082-2020-MRNA-1273-P301000001
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

SAEID	USA-US082-2020-MRNA-1273-P301000001
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 11:06
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

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

SAEID	USA-US082-2020-MRNA-1273-P301000001
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/OCT/2020 10:29
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

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

SAEID	USA-US082-2020-MRNA-1273-P301000001
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/OCT/2020 19:25
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

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 23:11:57

Generated On: 09 Jun 2021 17:33:17

SAEID	USA-US082-2020-MRNA-1273-P301000001
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/OCT/2020 10:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3422135 (Prod: Vanderbilt University Medical Center)

US3422135

Form: Participant Creation

Generated On: 09 Jun 2021 17:33:17

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:55:45
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered 'US3422135'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:34

US3422135

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:14
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:00:11

US3422135

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:14
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:34

US3422135

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:14
User entered 'Clinic (Clinic)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:00:11

US3422135

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'SCRN'	System	28 Aug 2020 14:00:11

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:35

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '67'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'YEARS'	System	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '67'	System	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered 'Male (M)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered 'I'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '0'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '0'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '0'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '0'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '0'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered empty.	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '0'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:33:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:10:08
User entered '0'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:08

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered '28 Aug 2020'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Aug 2020'	System	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '2020'	System	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered 'Amendment 3 (3)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered empty.	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered empty.	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered 'No (N)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:31

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:34:34

US3422135

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:33:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'I'	System	28 Aug 2020 14:01:39

US3422135

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:56:35
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
User closed query 'Source is not complete for Inclusion criteria. Please update as needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:56:14
Query 'Source is not complete for Inclusion criteria. Please update as needed.' answered with 'corrected' (Site from CRA).	Naomi Kown (b) (4) (b) (4)	22 Sep 2020 15:52:03
User opened query 'Source is not complete for Inclusion criteria. Please update as needed.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:24:13
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:39

US3422135

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:33:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:26:58
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:13:36

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:42
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:15:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:15:46
Data point term sent to Coder	System	28 Aug 2020 15:14:36
User entered 'Hypothyroidism'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:45:08
User entered 'un UNK 1984' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:45:08
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:27:45
User entered '30 Jun 1984'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:47
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:52
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:27:55
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jan 1984'	System	16 Oct 2020 18:45:08
User entered 'Jun 1984'	System	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '1984'	System	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:13:59

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:28:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:15:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:15:45
Data point term sent to Coder	System	28 Aug 2020 15:14:36
User entered 'Hypercholesterolemia'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:45:39
User entered 'un UNK 1994' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:45:39
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:28:11
User entered '30 Jun 1994'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:28:14
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:28:19
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:28:22
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:28:24
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jan 1994'	System	16 Oct 2020 18:45:39
User entered 'Jun 1994'	System	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '1994'	System	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:14:25

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:29:00
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:16:43
Data point term sent to Coder	System	28 Aug 2020 15:15:37
User entered 'Hypertension'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:46:07
User entered 'un UNK 2003' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:46:07
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:29:03
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	28 Aug 2020 15:14:49
User entered '30 Jun 2003' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:49
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	28 Aug 2020 15:14:37
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:29:34
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:29:36
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:14:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 15:14:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:14:37
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:29:39
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:29:45
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jan 2003'	System	16 Oct 2020 18:46:07
User entered 'Jun 2003'	System	28 Aug 2020 15:14:49
User entered empty.	System	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '2003'	System	28 Aug 2020 15:14:49
User entered empty.	System	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:14:37

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:29:54
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:16:43
Data point term sent to Coder	System	28 Aug 2020 15:15:37
User entered 'Diabetes type II'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
User entered 'UN UNK 2006' reason for change: New Information	Naomi Kown (b) (4) (b) (4)	27 Oct 2020 18:14:20
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:46:33
User entered 'un UNK 2016' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:46:33
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:29:56
User entered '30 Jun 2016'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:29:58
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:00
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:03
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:04
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jan 2006'	System	27 Oct 2020 18:14:20
User entered 'Jan 2016'	System	16 Oct 2020 18:46:33
User entered 'Jun 2016'	System	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '2006'	System	27 Oct 2020 18:14:20
User entered '2016'	System	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:15:18

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:12
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:16:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:16:42
Data point term sent to Coder	System	28 Aug 2020 15:15:40
User entered 'Seasonal allergies'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 18:47:03
User entered 'un UNK 2018' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:47:03
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:30:14
User entered '30 Jun 2018'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:38
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:39
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:42
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:30:45
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jan 2018'	System	16 Oct 2020 18:47:03
User entered 'Jun 2018'	System	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '2018'	System	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:15:38

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:01
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:17:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:17:40
Data point term sent to Coder	System	28 Aug 2020 15:16:41
User entered 'General anxiety'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:14
User entered 'un UNK 2018' reason for change: New Information	(b) (4), (b) (6)	23 Oct 2020 17:01:14
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:31:03
User entered '30 Jun 2018'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:04
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:07
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:09
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:10
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jan 2018'	System	23 Oct 2020 17:01:14
User entered 'Jun 2018'	System	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '2018'	System	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:16:00

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:16
User coded data point as SOC: Nervous system disorders, HLG: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:17:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:17:40
Data point term sent to Coder	System	28 Aug 2020 15:16:41
User entered 'Sciatica'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:38
User entered 'un UNK 2019' reason for change: New Information	(b) (4), (b) (6)	23 Oct 2020 17:01:38
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:31:19
User entered '30 Jun 2019'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:40
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:43
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:44
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:31:45
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jan 2019'	System	23 Oct 2020 17:01:38
User entered 'Jun 2019'	System	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '2019'	System	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	28 Aug 2020 15:16:20

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 18:41:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:41:51
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:01:30
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Specific allergy (drug) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Nov 2020 11:15:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Nov 2020 11:15:50
Data point term sent to Coder	System	23 Oct 2020 17:04:50
User entered 'allergy alpha-gel'	(b) (4), (b) (6)	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
User entered 'un Jun 2019'	(b) (4), (b) (6)	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:30
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'Jun 2019'	System	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '2019'	System	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered empty.	System	23 Oct 2020 17:04:18

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:17
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:19
User entered '28 Aug 2020'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:24
User entered '08:41'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '28 Aug 2020 08:41'	System	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:32:58
User entered '66' in	Cindy Trimmer (b) (4)	28 Aug 2020 15:17:01
DataPoint set to visible.	(b) (4) System	28 Aug 2020 14:01:39

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:33:00
User entered '200' lb	Cindy Trimmer (b) (4)	28 Aug 2020 15:17:01
DataPoint set to visible.	(b) (4) System	28 Aug 2020 14:01:39

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered '32.34834'	System	28 Aug 2020 15:17:01
DataPoint set to visible.	System	28 Aug 2020 14:01:39

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'kg/m2'	System	28 Aug 2020 15:17:01
DataPoint set to visible.	System	28 Aug 2020 14:01:39

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:05
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:19:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:03:11
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:43
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:31:10
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:31:10
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:21:08
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:42:18
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:42:18
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:05
Query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:02
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 21:11:58
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:58

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:33:47
User entered '98.1' F	Cindy Trimmer (b) (4)	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:05
DataPoint Un-verified.	Cindy Trimmer (b) (4)	21 Sep 2020 21:11:58
User entered empty; reason for change Data Entry Error	(b) (4) Cindy Trimmer (b) (4)	21 Sep 2020 21:11:58
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:33:50
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:33:52
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:05
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:19:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:03:13
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:43
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:27:43
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:27:43
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:21:13
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:42:38
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:42:38
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:11
Query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:08
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 21:11:58
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:58

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Folder: Screening

Form: Vital Signs

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:33:59
User entered '77'	Cindy Trimmer (b) (4)	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'bpm'	System	25 Sep 2020 14:41:43
User entered empty.	System	21 Sep 2020 21:11:58
User entered 'bpm'	System	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:05
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:19:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:03:15
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:43
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:27:57
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:27:57
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:21:18
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:42:51
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:42:51
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:16
Query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:13
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 21:11:58
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:58

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:34:10
User entered '14'	Cindy Trimmer (b) (4)	28 Aug 2020 15:17:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'breaths/min'	System	25 Sep 2020 14:41:43
User entered empty.	System	21 Sep 2020 21:11:58
User entered 'breaths/min'	System	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:05
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:19:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:03:17
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:43
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:28:49
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:28:49
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:21:24
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:43:00
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:43:00
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:22
Query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:19
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 21:11:58
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:58

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Folder: Screening

Form: Vital Signs

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Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:34:16
User entered '118'	Cindy Trimmer (b) (4)	28 Aug 2020 15:17:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'mmHg'	System	25 Sep 2020 14:41:43
User entered empty.	System	21 Sep 2020 21:11:58
User entered 'mmHg'	System	28 Aug 2020 15:17:01

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:05
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:19:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:03:19
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:41:43
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:28:59
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:28:59
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:21:28
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:43:10
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:43:10
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:27
Query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:12:24
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 21:11:58
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:58

US3422135

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Visit 1 vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:34:22
User entered '64'	Cindy Trimmer (b) (4)	28 Aug 2020 15:17:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User entered 'mmHg'	System	25 Sep 2020 14:41:43
User entered empty.	System	21 Sep 2020 21:11:58
User entered 'mmHg'	System	28 Aug 2020 15:17:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01

US3422135

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:00
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:17:14

US3422135

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:00
User entered '28 Aug 2020'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:17:14

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'babysit 6 grandchildren, frequent visits to stores weekly, weekly golf team'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

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)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered 'I'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:33:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:49:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:09:44
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:20:05

US3422135

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:53:35
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:56

US3422135

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:53:35
User entered '28 Aug 2020'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:56

US3422135

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

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 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:53:35
User entered 'Clinic (Clinic)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:01:56

US3422135

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'VISIT1'	System	28 Aug 2020 14:01:56

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:54:25

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered '188199'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:54:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:54:25

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:29:59

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:29:59

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:29:59

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:29:59

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:33
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:29:59

US3422135

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:33:17

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:56:17
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4)	21 Sep 2020 21:11:41
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:23:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:23:53

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:52
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:20:43
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:18
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:32
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:32
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:49:30
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:14
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:14
Query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:32
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:28
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:34:54
User entered '66' in	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:55
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:20:47
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:18
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:42
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:42
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:49:32
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:26
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:26
Query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:35
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:28
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 15:34:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:34:56
User entered '200' lb	Cindy Trimmer (b) (4)	28 Aug 2020 15:31:12
	(b) (4)	

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:52
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:20:43
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:18
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:32
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:32
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:49:30
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:14
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:14
Query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:32
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:28
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:34:54
User entered '66' in	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:55
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 18:20:47
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:18
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:42
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:42
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:49:32
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:26
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:26
Query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:35
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:28
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 15:34:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:34:56
User entered '200' lb	Cindy Trimmer (b) (4)	28 Aug 2020 15:31:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:18
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:19
User entered '28 Aug 2020'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:21
User entered '08:41'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '28 Aug 2020 08:41'	System	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:35:23
User entered '98.1' F	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:40:58
User closed query 'Per source, route is indicated as Oral. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:55
Query 'Per source, route is indicated as Oral. Please confirm and update as needed.' answered with 'corrected' (Site from CRA).	Naomi Kown (b) (4) (b) (4)	22 Sep 2020 17:31:50
User entered 'Oral (Oral)' reason for change: Data Entry Error	Naomi Kown (b) (4) (b) (4)	22 Sep 2020 17:31:43
User opened query 'Per source, route is indicated as Oral. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:36:02
DataPoint Un-verified.		17 Sep 2020 15:35:27
DataPoint Verified.		17 Sep 2020 15:35:24
User entered 'Axillary (Axillary)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:06
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:08
User entered '77'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'bpm'	System	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:10
User entered '014'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'breaths/min'	System	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:14
User entered '118'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:15
User entered '64'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:20:52
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).		25 Sep 2020 18:20:43
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:42:18
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:32
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:32
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	23 Sep 2020 16:49:30
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:14
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).		23 Sep 2020 14:40:14
Query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:32
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 21:11:28
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:34:54
User entered '66' in	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 18:20:55
User closed query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).		25 Sep 2020 18:20:47
Query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' answered with 'corrected' (Site from CRA).	Cindy Trimmer (b) (4)	25 Sep 2020 14:42:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4)	25 Sep 2020 14:42:18
User opened query 'Please enter Not Done in the data field, save the response and then reply to the query and save.Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:42
User closed query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:30:42
Query ' Please enter Not Done in the data field of the edc. Thank you' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4)	23 Sep 2020 16:49:32
User opened query ' Please enter Not Done in the data field of the edc. Thank you' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:40:26
User closed query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).		23 Sep 2020 14:40:26
Query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' answered with 'ND' (Site from CRA).	Cindy Trimmer (b) (4)	21 Sep 2020 21:11:35
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 21:11:28
User opened query 'Please remove data and enter ND (Not Done) as this should be entered on Screening vitals only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 15:34:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:33:17

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:34:56
User entered '200' lb	Cindy Trimmer (b) (4)	28 Aug 2020 15:31:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:22
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 17:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 17:45:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	15 Sep 2020 17:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:31:12
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:25
User entered '28 Aug 2020'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:28
User entered '09:52'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '28 Aug 2020 09:52'	System	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:35
User entered '97.3' F	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:37
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:39
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:47
User entered '76'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'bpm'	System	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:36:58
User entered '14'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'breaths/min'	System	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:01
User entered '105'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
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)	29 Sep 2020 09:29:58
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 18:21:11
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 'ncs' (Site from System).	Naomi Kown (b) (4) (b) (4)	22 Sep 2020 17:32:09
Amendment Manager: 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).	System	17 Sep 2020 00:09:10
User entered '057'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	28 Aug 2020 15:31:12

US3422135

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:41:27
User closed query 'Please remove data and enter ND (Not Done) as this should be entered at Screening only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:41:22
Query 'Please remove data and enter ND (Not Done) as this should be entered at Screening only per eCRF guidelines.' answered with 'Nd' (Site from CRA).	Naomi Kown (b) (4)	22 Sep 2020 16:18:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 16:18:05
User opened query 'Please remove data and enter ND (Not Done) as this should be entered at Screening only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:40:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:31:25

US3422135

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:41:27
User closed query 'Please remove data and enter ND (Not Done) as this should be entered at Screening only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:41:24
Query 'Please remove data and enter ND (Not Done) as this should be entered at Screening only per eCRF guidelines.' answered with 'Nd' (Site from CRA).	Naomi Kown (b) (4)	22 Sep 2020 16:18:14
User entered empty; reason for change Data Entry Error	(b) (4)	22 Sep 2020 16:18:05
User opened query 'Please remove data and enter ND (Not Done) as this should be entered at Screening only per eCRF guidelines.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 15:40:28
User entered '28 Aug 2020'	Cindy Trimmer (b) (4)	28 Aug 2020 15:31:25

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:00
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:00
User entered empty.	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

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 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:00
User entered empty.	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:00
User entered '28 Aug 2020'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:00
User entered '09:22'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered '28 Aug 2020 09:22'	System	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:00
User entered 'Right Arm (RIGHT ARM)'	Naomi Kown (b) (4) (b) (4)	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 15:55:00
User entered 'ONCE'	System	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 14:30:27

US3422135

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:53:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:43

US3422135

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:53:55
User entered '28 Aug 2020'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:43

US3422135

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:53:55
User entered '08:47'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:43

US3422135

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered '28 Aug 2020 08:47'	System	28 Aug 2020 15:31:43

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:05
User entered '28 Aug 2020'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:05
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:05
User entered '08:45'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered '28 Aug 2020 08:45'	System	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:05
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:05
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered empty.	System	28 Aug 2020 15:31:58

US3422135

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:12
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:32:03

US3422135

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered '1'	System	28 Aug 2020 15:32:03

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T09:58:03', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'f3bf7429-d153-47f7-a34a-6073868f9bae' User entered 'Yes (Y)'	System	28 Aug 2020 14:58:52
	System	28 Aug 2020 14:58:52

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T09:58:28', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'f3bf7429-d153-47f7-a34a-6073868f9bae' User entered '97.3'	System	28 Aug 2020 14:58:52
	System	28 Aug 2020 14:58:52

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T09:58:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'f3bf7429-d153-47f7-a34a-6073868f9bae'	System	28 Aug 2020 14:58:52
User entered 'No (N)'	System	28 Aug 2020 14:58:52

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T09:58:48', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'f3bf7429-d153-47f7-a34a-6073868f9bae' User entered '28 Aug 2020 09:58'	System	28 Aug 2020 14:58:52
	System	28 Aug 2020 14:58:52

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 09:42'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 12:12'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:37:15', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5f32894d-5e70-42f8-8a13-77603d8ce97f' User entered 'Yes (Y)'	System	29 Aug 2020 05:37:57
	System	29 Aug 2020 05:37:57

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:37:38', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5f32894d-5e70-42f8-8a13-77603d8ce97f' User entered '97.8'	System	29 Aug 2020 05:37:57
	System	29 Aug 2020 05:37:57

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:37:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5f32894d-5e70-42f8-8a13-77603d8ce97f' User entered 'No (N)'	System	29 Aug 2020 05:37:57
	System	29 Aug 2020 05:37:57

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:37:53', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5f32894d-5e70-42f8-8a13-77603d8ce97f' User entered '29 Aug 2020 00:37'	System	29 Aug 2020 05:37:57
	System	29 Aug 2020 05:37:57

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 13:07'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 2'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:13:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86e828da-9bb5-45b7-8d7f-91d43188d499'	System	30 Aug 2020 15:14:18
User entered 'Yes (Y)'	System	30 Aug 2020 15:14:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:03', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86e828da-9bb5-45b7-8d7f-91d43188d499' User entered '98.3'	System	30 Aug 2020 15:14:18
	System	30 Aug 2020 15:14:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86e828da-9bb5-45b7-8d7f-91d43188d499'	System	30 Aug 2020 15:14:18
User entered 'No (N)'	System	30 Aug 2020 15:14:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:17', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86e828da-9bb5-45b7-8d7f-91d43188d499' User entered '30 Aug 2020 10:14'	System	30 Aug 2020 15:14:18
	System	30 Aug 2020 15:14:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 3'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:01:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'edd02e41-d9ad-435a-87be-ba0eab78cf0e' User entered 'Yes (Y)'	System	31 Aug 2020 12:02:09
	System	31 Aug 2020 12:02:09

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:01:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'edd02e41-d9ad-435a-87be-ba0eab78cf0e' User entered '98.3'	System	31 Aug 2020 12:02:09
	System	31 Aug 2020 12:02:09

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:00', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'edd02e41-d9ad-435a-87be-ba0eab78cf0e' User entered 'No (N)'	System	31 Aug 2020 12:02:09
	System	31 Aug 2020 12:02:09

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:07', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'edd02e41-d9ad-435a-87be-ba0eab78cf0e' User entered '31 Aug 2020 07:02'	System	31 Aug 2020 12:02:09
	System	31 Aug 2020 12:02:09

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 4'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:03', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'beddf0df-0134-44d1-b631-327461f17ccf' User entered 'Yes (Y)'	System	01 Sep 2020 15:21:29
	System	01 Sep 2020 15:21:29

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'beddf0df-0134-44d1-b631-327461f17ccf' User entered '98.3'	System	01 Sep 2020 15:21:29
	System	01 Sep 2020 15:21:29

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'beddf0df-0134-44d1-b631-327461f17ccf'	System	01 Sep 2020 15:21:29
User entered 'No (N)'	System	01 Sep 2020 15:21:29

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'beddf0df-0134-44d1-b631-327461f17ccf' User entered '01 Sep 2020 10:21'	System	01 Sep 2020 15:21:29
	System	01 Sep 2020 15:21:29

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 5'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:19', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'dd0a13d0-dc86-4257-bb14-16c2919f4f35'	System	02 Sep 2020 16:03:18
User entered 'Yes (Y)'	System	02 Sep 2020 16:03:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'dd0a13d0-dc86-4257-bb14-16c2919f4f35' User entered '98.3'	System	02 Sep 2020 16:03:18
	System	02 Sep 2020 16:03:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'dd0a13d0-dc86-4257-bb14-16c2919f4f35'	System	02 Sep 2020 16:03:18
User entered 'No (N)'	System	02 Sep 2020 16:03:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'dd0a13d0-dc86-4257-bb14-16c2919f4f35'	System	02 Sep 2020 16:03:18
User entered '02 Sep 2020 11:02'	System	02 Sep 2020 16:03:18

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 6'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:22:46', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86a10673-7a9c-4936-a062-803cac13fc89' User entered 'Yes (Y)'	System	03 Sep 2020 15:23:12
	System	03 Sep 2020 15:23:12

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:22:54', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86a10673-7a9c-4936-a062-803cac13fc89' User entered '98.0'	System	03 Sep 2020 15:23:12
	System	03 Sep 2020 15:23:12

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86a10673-7a9c-4936-a062-803cac13fc89'	System	03 Sep 2020 15:23:12
User entered 'No (N)'	System	03 Sep 2020 15:23:12

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:07', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '86a10673-7a9c-4936-a062-803cac13fc89' User entered '03 Sep 2020 10:23'	System	03 Sep 2020 15:23:12
	System	03 Sep 2020 15:23:12

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 7'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:00', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26303847-c5a7-46e6-8b29-46f08d00049e' User entered 'Yes (Y)'	System	04 Sep 2020 15:28:26
	System	04 Sep 2020 15:28:26

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26303847-c5a7-46e6-8b29-46f08d00049e' User entered '98.4'	System	04 Sep 2020 15:28:26
	System	04 Sep 2020 15:28:26

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26303847-c5a7-46e6-8b29-46f08d00049e' User entered 'No (N)'	System	04 Sep 2020 15:28:26
	System	04 Sep 2020 15:28:26

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26303847-c5a7-46e6-8b29-46f08d00049e' User entered '04 Sep 2020 10:28'	System	04 Sep 2020 15:28:26
	System	04 Sep 2020 15:28:26

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T09:59:25', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a855586-5a21-4a98-b0c9-587a7df1c565'	System	28 Aug 2020 15:01:01
User entered 'None (1)'	System	28 Aug 2020 15:01:01

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:00:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a855586-5a21-4a98-b0c9-587a7df1c565' User entered 'No (N)'	System	28 Aug 2020 15:01:01
	System	28 Aug 2020 15:01:01

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:00:24', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a855586-5a21-4a98-b0c9-587a7df1c565'	System	28 Aug 2020 15:01:01
User entered 'No (N)'	System	28 Aug 2020 15:01:01

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:00:45', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a855586-5a21-4a98-b0c9-587a7df1c565'	System	28 Aug 2020 15:01:01
User entered 'None (1)'	System	28 Aug 2020 15:01:01

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:00:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a855586-5a21-4a98-b0c9-587a7df1c565' User entered '28 Aug 2020 10:00'	System	28 Aug 2020 15:01:01
	System	28 Aug 2020 15:01:01

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 09:42'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 12:12'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:38:21', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '6e7faff5-6086-4243-aae7-142511a18248'	System	29 Aug 2020 05:38:54
User entered 'None (1)'	System	29 Aug 2020 05:38:54

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:38:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '6e7faff5-6086-4243-aae7-142511a18248'	System	29 Aug 2020 05:38:54
User entered 'No (N)'	System	29 Aug 2020 05:38:54

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:38:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '6e7faff5-6086-4243-aae7-142511a18248'	System	29 Aug 2020 05:38:54
User entered 'No (N)'	System	29 Aug 2020 05:38:54

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:38:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '6e7faff5-6086-4243-aae7-142511a18248'	System	29 Aug 2020 05:38:54
User entered 'None (1)'	System	29 Aug 2020 05:38:54

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:38:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '6e7faff5-6086-4243-aae7-142511a18248' User entered '29 Aug 2020 00:38'	System	29 Aug 2020 05:38:54
	System	29 Aug 2020 05:38:54

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 13:07'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 2'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:32', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '09553860-8e17-46f0-90d4-2614189ddb12'	System	30 Aug 2020 15:14:52
User entered 'None (1)'	System	30 Aug 2020 15:14:52

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:35', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '09553860-8e17-46f0-90d4-2614189ddb12'	System	30 Aug 2020 15:14:52
User entered 'No (N)'	System	30 Aug 2020 15:14:52

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:39', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '09553860-8e17-46f0-90d4-2614189ddb12'	System	30 Aug 2020 15:14:52
User entered 'No (N)'	System	30 Aug 2020 15:14:52

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '09553860-8e17-46f0-90d4-2614189ddb12'	System	30 Aug 2020 15:14:52
User entered 'None (1)'	System	30 Aug 2020 15:14:52

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:48', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '09553860-8e17-46f0-90d4-2614189ddb12'	System	30 Aug 2020 15:14:52
User entered '30 Aug 2020 10:14'	System	30 Aug 2020 15:14:52

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 3'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '41719ce5-b91a-48c4-869c-cf33e6ee55d8'	System	31 Aug 2020 12:02:39
User entered 'None (1)'	System	31 Aug 2020 12:02:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '41719ce5-b91a-48c4-869c-cf33e6ee55d8'	System	31 Aug 2020 12:02:39
User entered 'No (N)'	System	31 Aug 2020 12:02:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '41719ce5-b91a-48c4-869c-cf33e6ee55d8'	System	31 Aug 2020 12:02:39
User entered 'No (N)'	System	31 Aug 2020 12:02:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:31', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '41719ce5-b91a-48c4-869c-cf33e6ee55d8' User entered 'None (1)'	System	31 Aug 2020 12:02:39
	System	31 Aug 2020 12:02:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:36', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '41719ce5-b91a-48c4-869c-cf33e6ee55d8' User entered '31 Aug 2020 07:02'	System	31 Aug 2020 12:02:39
	System	31 Aug 2020 12:02:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 4'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:35', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '60103084-b67f-445f-8d8a-2a4c2a635200'	System	01 Sep 2020 15:21:55
User entered 'None (1)'	System	01 Sep 2020 15:21:55

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:39', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '60103084-b67f-445f-8d8a-2a4c2a635200'	System	01 Sep 2020 15:21:55
User entered 'No (N)'	System	01 Sep 2020 15:21:55

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:42', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '60103084-b67f-445f-8d8a-2a4c2a635200' User entered 'No (N)'	System	01 Sep 2020 15:21:55
	System	01 Sep 2020 15:21:55

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:47', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '60103084-b67f-445f-8d8a-2a4c2a635200'	System	01 Sep 2020 15:21:55
User entered 'None (1)'	System	01 Sep 2020 15:21:55

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:50', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '60103084-b67f-445f-8d8a-2a4c2a635200' User entered '01 Sep 2020 10:21'	System	01 Sep 2020 15:21:55
	System	01 Sep 2020 15:21:55

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 5'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:40', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '08e2993e-af74-40cd-ac40-2606e8384840' User entered 'None (1)'	System	02 Sep 2020 16:03:47
	System	02 Sep 2020 16:03:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '08e2993e-af74-40cd-ac40-2606e8384840' User entered 'No (N)'	System	02 Sep 2020 16:03:47
	System	02 Sep 2020 16:03:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:47', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '08e2993e-af74-40cd-ac40-2606e8384840' User entered 'No (N)'	System	02 Sep 2020 16:03:47
	System	02 Sep 2020 16:03:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:02:57', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '08e2993e-af74-40cd-ac40-2606e8384840' User entered 'None (1)'	System	02 Sep 2020 16:03:47
	System	02 Sep 2020 16:03:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:00', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '08e2993e-af74-40cd-ac40-2606e8384840' User entered '02 Sep 2020 11:03'	System	02 Sep 2020 16:03:47
	System	02 Sep 2020 16:03:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 6'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4c826f74-816c-4b27-b3e9-2d415c50fddc'	System	03 Sep 2020 15:23:39
User entered 'None (1)'	System	03 Sep 2020 15:23:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4c826f74-816c-4b27-b3e9-2d415c50fddc' User entered 'No (N)'	System	03 Sep 2020 15:23:39
	System	03 Sep 2020 15:23:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4c826f74-816c-4b27-b3e9-2d415c50fddc' User entered 'No (N)'	System	03 Sep 2020 15:23:39
	System	03 Sep 2020 15:23:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:33', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4c826f74-816c-4b27-b3e9-2d415c50fddc' User entered 'None (1)'	System	03 Sep 2020 15:23:39
	System	03 Sep 2020 15:23:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:37', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4c826f74-816c-4b27-b3e9-2d415c50fddc' User entered '03 Sep 2020 10:23'	System	03 Sep 2020 15:23:39
	System	03 Sep 2020 15:23:39

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 7'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26a519d7-9c70-488b-ba56-1ac90737a142'	System	04 Sep 2020 15:28:47
User entered 'None (1)'	System	04 Sep 2020 15:28:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26a519d7-9c70-488b-ba56-1ac90737a142'	System	04 Sep 2020 15:28:47
User entered 'No (N)'	System	04 Sep 2020 15:28:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:38', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26a519d7-9c70-488b-ba56-1ac90737a142' User entered 'No (N)'	System	04 Sep 2020 15:28:47
	System	04 Sep 2020 15:28:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:42', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26a519d7-9c70-488b-ba56-1ac90737a142'	System	04 Sep 2020 15:28:47
User entered 'None (1)'	System	04 Sep 2020 15:28:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:46', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '26a519d7-9c70-488b-ba56-1ac90737a142'	System	04 Sep 2020 15:28:47
User entered '04 Sep 2020 10:28'	System	04 Sep 2020 15:28:47

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:07', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692' User entered 'None (0)'	System	28 Aug 2020 15:01:41
	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692' User entered 'None (0)'	System	28 Aug 2020 15:01:41
	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:15', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692' User entered 'None (0)'	System	28 Aug 2020 15:01:41
	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:19', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692' User entered 'None (0)'	System	28 Aug 2020 15:01:41
	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692' User entered 'None (0)'	System	28 Aug 2020 15:01:41
	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:25', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692' User entered 'None (0)'	System	28 Aug 2020 15:01:41
	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:32', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692'	System	28 Aug 2020 15:01:41
User entered 'No (N)'	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-28T10:01:37', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '52a071c6-8f90-4741-ac3c-4efab2776692' User entered '28 Aug 2020 10:01'	System	28 Aug 2020 15:01:41
	System	28 Aug 2020 15:01:41

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 09:42'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 12:12'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:38:58', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0'	System	29 Aug 2020 05:39:35
User entered 'None (0)'	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:39:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0' User entered 'None (0)'	System	29 Aug 2020 05:39:35
	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:39:05', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0' User entered 'None (0)'	System	29 Aug 2020 05:39:35
	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:39:08', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0' User entered 'None (0)'	System	29 Aug 2020 05:39:35
	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:39:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0' User entered 'None (0)'	System	29 Aug 2020 05:39:35
	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:39:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0' User entered 'None (0)'	System	29 Aug 2020 05:39:35
	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:39:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0'	System	29 Aug 2020 05:39:35
User entered 'No (N)'	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-29T00:39:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4e3e5c79-9798-4783-970a-04baef87b7c0' User entered '29 Aug 2020 00:39'	System	29 Aug 2020 05:39:35
	System	29 Aug 2020 05:39:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Aug 2020 13:07'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 2'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:14:57', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered 'None (0)'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:15:02', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered 'None (0)'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:15:06', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered 'None (0)'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:15:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered 'None (0)'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:15:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered 'None (0)'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:15:21', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered 'None (0)'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:15:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered 'No (N)'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-30T10:15:32', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '58b518ac-9f77-4e77-b664-daa92404a0fe' User entered '30 Aug 2020 10:15'	System	30 Aug 2020 15:15:35
	System	30 Aug 2020 15:15:35

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 3'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered 'None (0)'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered 'None (0)'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:48', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered 'None (0)'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered 'None (0)'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:56', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered 'None (0)'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:02:59', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered 'None (0)'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:03:08', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered 'No (N)'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-08-31T07:03:12', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e916a459-e13a-4ec6-b062-8befba19415f' User entered '31 Aug 2020 07:03'	System	31 Aug 2020 12:03:15
	System	31 Aug 2020 12:03:15

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 4'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b' User entered 'None (0)'	System	01 Sep 2020 15:22:24
	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:21:58', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b' User entered 'None (0)'	System	01 Sep 2020 15:22:24
	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:22:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b' User entered 'None (0)'	System	01 Sep 2020 15:22:24
	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:22:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b' User entered 'None (0)'	System	01 Sep 2020 15:22:24
	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:22:07', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b' User entered 'None (0)'	System	01 Sep 2020 15:22:24
	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:22:09', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b' User entered 'None (0)'	System	01 Sep 2020 15:22:24
	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:22:17', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b'	System	01 Sep 2020 15:22:24
User entered 'No (N)'	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-01T10:22:21', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e1a2bf7d-56bd-40d4-863f-9a59aeb25f4b' User entered '01 Sep 2020 10:22'	System	01 Sep 2020 15:22:24
	System	01 Sep 2020 15:22:24

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 5'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:05', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered 'None (0)'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:08', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered 'None (0)'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered 'None (0)'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered 'None (0)'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:17', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered 'None (0)'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:19', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered 'None (0)'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered 'No (N)'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-02T11:03:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8aa4cbbe-6d8c-4c4c-b0e5-a9a2d43a249d' User entered '02 Sep 2020 11:03'	System	02 Sep 2020 16:04:09
	System	02 Sep 2020 16:04:09

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 6'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753'	System	03 Sep 2020 15:24:19
User entered 'None (0)'	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:48', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753' User entered 'None (0)'	System	03 Sep 2020 15:24:19
	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:53', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753' User entered 'None (0)'	System	03 Sep 2020 15:24:19
	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:23:57', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753' User entered 'None (0)'	System	03 Sep 2020 15:24:19
	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:24:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753' User entered 'None (0)'	System	03 Sep 2020 15:24:19
	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:24:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753' User entered 'None (0)'	System	03 Sep 2020 15:24:19
	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:24:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753'	System	03 Sep 2020 15:24:19
User entered 'No (N)'	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-03T10:24:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4f4ad1d5-633b-440d-8972-af256dbbd753'	System	03 Sep 2020 15:24:19
User entered '03 Sep 2020 10:24'	System	03 Sep 2020 15:24:19

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 7'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:56', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered 'None (0)'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:28:59', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered 'None (0)'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:29:02', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered 'None (0)'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:29:08', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered 'None (0)'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:29:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered 'None (0)'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:29:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered 'None (0)'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:29:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered 'No (N)'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-04T10:29:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aa8841b4-702b-4e36-96b8-3725f1f29315' User entered '04 Sep 2020 10:29'	System	04 Sep 2020 15:29:29
	System	04 Sep 2020 15:29:29

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:30:27

US3422135

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:59:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:35:12

US3422135

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:59:59
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:35:12

US3422135

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:59:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 20:35:12

US3422135

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:59:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:35:12

US3422135

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:00:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:35:20

US3422135

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'I'	System	04 Sep 2020 20:35:20

US3422135

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:09:49
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	14 Sep 2020 13:20:28

US3422135

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:09:49
User entered '11 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	14 Sep 2020 13:20:28

US3422135

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:09:49
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4) (b) (4)	14 Sep 2020 13:20:28

US3422135

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:09:49
User entered empty.	Cindy Trimmer (b) (4)	14 Sep 2020 13:20:28

US3422135

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:09:52
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	14 Sep 2020 13:20:32

US3422135

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'I'	System	14 Sep 2020 13:20:32

US3422135

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:09:34
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	21 Sep 2020 13:47:16

US3422135

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:09:34
User entered '18 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 13:47:16

US3422135

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:09:34
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 13:47:16

US3422135

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:09:34
User entered empty.	Cindy Trimmer (b) (4)	21 Sep 2020 13:47:16

US3422135

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:09:39
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 13:47:20

US3422135

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'I'	System	21 Sep 2020 13:47:20

US3422135

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:53:49

US3422135

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:49
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:53:49

US3422135

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[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 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Sep 2020 17:53:49

US3422135

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'VISIT2'	System	25 Sep 2020 17:53:49

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User closed query 'Source notes that Time of pre-dose vitals were taken at 8:50 am. Time of dose also at 8:50. Please verify correct entry.' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 17:57:01
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
Query 'Source notes that Time of pre-dose vitals were taken at 8:50 am. Time of dose also at 8:50. Please verify correct entry.' answered with 'corrected' (Site from CRA).	Naomi Kown (b) (4)	27 Oct 2020 18:12:00
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:20:58
User opened query 'Source notes that Time of pre-dose vitals were taken at 8:50 am. Time of dose also at 8:50. Please verify correct entry.' (Site from CRA).		14 Oct 2020 15:11:11
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	25 Sep 2020 21:02:01
User entered '08:10' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	25 Sep 2020 21:02:01
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	25 Sep 2020 17:56:22
User entered '08:50'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '25 Sep 2020 08:10'	System	25 Sep 2020 21:02:01
User entered '25 Sep 2020 08:50'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '098.6' F	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '079'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'bpm'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '14'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'breaths/min'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '126'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '070'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '09:20'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '25 Sep 2020 09:20'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '098.5' F	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '068'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'bpm'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '016'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'breaths/min'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User entered '115'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:58
User closed query 'Per CDM: Please indicate if the out of range value is considered as CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 05:37:56
Query 'Per CDM: Please indicate if the out of range value is considered as CS/NCS. If CS, please report as AE as appropriate.' answered with 'NCS' (Site from DM).	Wendy Winn (b) (4) (b) (4)	29 Sep 2020 17:08:37
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) (6)	29 Sep 2020 09:35:04
User opened query 'Per CDM: Please indicate if the out of range value is considered as CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:35:02
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 'corrected.' (Site from System).	April Hanlotxomphou (b) (4)	25 Sep 2020 21:02:50
User entered '58' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	25 Sep 2020 21:02:40
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).	System	25 Sep 2020 17:56:22
User entered '058'	(b) (4), (b) (6)	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	25 Sep 2020 17:56:22

US3422135

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:21:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:58:17

US3422135

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:21:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:58:17

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:23:24
User entered 'Yes (Y)'	Wendy Winn (b) (4) (b) (4)	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:23:24
User entered empty.	Wendy Winn (b) (4) (b) (4)	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

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 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:23:24
User entered empty.	Wendy Winn (b) (4) (b) (4)	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:23:24
User entered '25 Sep 2020'	Wendy Winn (b) (4) (b) (4)	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:23:24
User entered '08:50'	Wendy Winn (b) (4) (b) (4)	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '25 Sep 2020 08:50'	System	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:23:24
User entered 'Right Arm (RIGHT ARM)'	Wendy Winn (b) (4) (b) (4)	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:23:24
User entered 'ONCE'	System	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 13:52:27

US3422135

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:24:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:57:02

US3422135

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:24:08
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:57:02

US3422135

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:24:08
User entered '08:13'	(b) (4), (b) (6)	25 Sep 2020 17:57:02

US3422135

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '25 Sep 2020 08:13'	System	25 Sep 2020 17:57:02

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:26:47
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:26:47
User entered '08:15'	(b) (4), (b) (6)	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:33:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '25 Sep 2020 08:15'	System	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:26:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:26:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:33:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered empty.	System	25 Sep 2020 17:57:25

US3422135

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:26:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:57:36

US3422135

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '1'	System	25 Sep 2020 17:57:36

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:21:37', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '12901833-ce67-4ab6-9771-f7afce850fda' User entered 'Yes (Y)'	System	25 Sep 2020 14:22:19
	System	25 Sep 2020 14:22:19

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:21:56', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '12901833-ce67-4ab6-9771-f7afce850fda' User entered '98.5'	System	25 Sep 2020 14:22:19
	System	25 Sep 2020 14:22:19

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '12901833-ce67-4ab6-9771-f7afce850fda'	System	25 Sep 2020 14:22:19
User entered 'No (N)'	System	25 Sep 2020 14:22:19

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:15', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '12901833-ce67-4ab6-9771-f7afce850fda' User entered '25 Sep 2020 09:22'	System	25 Sep 2020 14:22:19
	System	25 Sep 2020 14:22:19

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 09:10'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 11:40'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:02', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b5363615-4c86-40b5-afc8-3b87a0195d0d' User entered 'Yes (Y)'	System	26 Sep 2020 16:11:26
	System	26 Sep 2020 16:11:26

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b5363615-4c86-40b5-afc8-3b87a0195d0d' User entered '99.0'	System	26 Sep 2020 16:11:26
	System	26 Sep 2020 16:11:26

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b5363615-4c86-40b5-afc8-3b87a0195d0d' User entered 'No (N)'	System	26 Sep 2020 16:11:26
	System	26 Sep 2020 16:11:26

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b5363615-4c86-40b5-afc8-3b87a0195d0d' User entered '26 Sep 2020 11:11'	System	26 Sep 2020 16:11:26
	System	26 Sep 2020 16:11:26

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 12:35'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 2'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T12:00:56', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '092896b6-0a13-46a5-ab2c-26f9525d3064' User entered 'Yes (Y)'	System	27 Sep 2020 14:01:44
	System	27 Sep 2020 14:01:44

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:01:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '092896b6-0a13-46a5-ab2c-26f9525d3064' User entered '100.1'	System	27 Sep 2020 14:01:44
	System	27 Sep 2020 14:01:44

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:01:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '092896b6-0a13-46a5-ab2c-26f9525d3064' User entered 'No (N)'	System	27 Sep 2020 14:01:44
	System	27 Sep 2020 14:01:44

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:01:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '092896b6-0a13-46a5-ab2c-26f9525d3064' User entered '27 Sep 2020 09:01'	System	27 Sep 2020 14:01:44
	System	27 Sep 2020 14:01:44

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 3'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:08:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e6043e42-3920-407a-9568-98dd27de31bb' User entered 'Yes (Y)'	System	28 Sep 2020 16:08:45
	System	28 Sep 2020 16:08:45

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:08:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e6043e42-3920-407a-9568-98dd27de31bb' User entered '97.9'	System	28 Sep 2020 16:08:45
	System	28 Sep 2020 16:08:45

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:08:39', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e6043e42-3920-407a-9568-98dd27de31bb'	System	28 Sep 2020 16:08:45
User entered 'No (N)'	System	28 Sep 2020 16:08:45

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:08:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e6043e42-3920-407a-9568-98dd27de31bb' User entered '28 Sep 2020 11:08'	System	28 Sep 2020 16:08:45
	System	28 Sep 2020 16:08:45

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 4'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:47:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025df2d6-ada8-4dcf-8c1b-78d591464b36' User entered 'Yes (Y)'	System	29 Sep 2020 12:48:30
	System	29 Sep 2020 12:48:30

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:47:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025df2d6-ada8-4dcf-8c1b-78d591464b36' User entered '98.7'	System	29 Sep 2020 12:48:30
	System	29 Sep 2020 12:48:30

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:48:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025df2d6-ada8-4dcf-8c1b-78d591464b36'	System	29 Sep 2020 12:48:30
User entered 'No (N)'	System	29 Sep 2020 12:48:30

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:48:28', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025df2d6-ada8-4dcf-8c1b-78d591464b36' User entered '29 Sep 2020 07:48'	System	29 Sep 2020 12:48:30
	System	29 Sep 2020 12:48:30

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 5'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8e6a0dfb-7981-4efa-9ffd-55b35a9b4542'	System	30 Sep 2020 16:07:29
User entered 'Yes (Y)'	System	30 Sep 2020 16:07:29

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8e6a0dfb-7981-4efa-9ffd-55b35a9b4542' User entered '99.1'	System	30 Sep 2020 16:07:29
	System	30 Sep 2020 16:07:29

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8e6a0dfb-7981-4efa-9ffd-55b35a9b4542'	System	30 Sep 2020 16:07:29
User entered 'No (N)'	System	30 Sep 2020 16:07:29

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8e6a0dfb-7981-4efa-9ffd-55b35a9b4542'	System	30 Sep 2020 16:07:29
User entered '30 Sep 2020 11:07'	System	30 Sep 2020 16:07:29

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 6'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:18:45', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '18415544-e0ea-449f-adee-2fd660a2258f' User entered 'Yes (Y)'	System	01 Oct 2020 13:19:10
	System	01 Oct 2020 13:19:10

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:18:51', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '18415544-e0ea-449f-adee-2fd660a2258f' User entered '99.2'	System	01 Oct 2020 13:19:10
	System	01 Oct 2020 13:19:10

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '18415544-e0ea-449f-adee-2fd660a2258f' User entered 'No (N)'	System	01 Oct 2020 13:19:10
	System	01 Oct 2020 13:19:10

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:05', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '18415544-e0ea-449f-adee-2fd660a2258f' User entered '01 Oct 2020 08:19'	System	01 Oct 2020 13:19:10
	System	01 Oct 2020 13:19:10

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 7'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:35:57', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e80f57e0-6e27-4181-b442-73d1f662e55e' User entered 'Yes (Y)'	System	02 Oct 2020 14:36:15
	System	02 Oct 2020 14:36:15

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e80f57e0-6e27-4181-b442-73d1f662e55e' User entered '98.4'	System	02 Oct 2020 14:36:15
	System	02 Oct 2020 14:36:15

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:08', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e80f57e0-6e27-4181-b442-73d1f662e55e' User entered 'No (N)'	System	02 Oct 2020 14:36:15
	System	02 Oct 2020 14:36:15

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:12', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e80f57e0-6e27-4181-b442-73d1f662e55e' User entered '02 Oct 2020 09:36'	System	02 Oct 2020 14:36:15
	System	02 Oct 2020 14:36:15

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:29', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd74e54b4-83b5-4fab-8fbd-740151834859'	System	25 Sep 2020 14:22:54
User entered 'None (1)'	System	25 Sep 2020 14:22:54

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd74e54b4-83b5-4fab-8fbd-740151834859'	System	25 Sep 2020 14:22:54
User entered 'No (N)'	System	25 Sep 2020 14:22:54

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:38', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd74e54b4-83b5-4fab-8fbd-740151834859'	System	25 Sep 2020 14:22:54
User entered 'No (N)'	System	25 Sep 2020 14:22:54

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:43', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd74e54b4-83b5-4fab-8fbd-740151834859'	System	25 Sep 2020 14:22:54
User entered 'None (1)'	System	25 Sep 2020 14:22:54

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:49', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd74e54b4-83b5-4fab-8fbd-740151834859' User entered '25 Sep 2020 09:22'	System	25 Sep 2020 14:22:54
	System	25 Sep 2020 14:22:54

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 09:10'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 11:40'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:38', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7922cb71-3ac8-41be-a169-664553b09635'	System	26 Sep 2020 16:12:15
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 16:12:15

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:42', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7922cb71-3ac8-41be-a169-664553b09635'	System	26 Sep 2020 16:12:15
User entered 'No (N)'	System	26 Sep 2020 16:12:15

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:45', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7922cb71-3ac8-41be-a169-664553b09635' User entered 'No (N)'	System	26 Sep 2020 16:12:15
	System	26 Sep 2020 16:12:15

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:11:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7922cb71-3ac8-41be-a169-664553b09635' User entered 'None (1)'	System	26 Sep 2020 16:12:15
	System	26 Sep 2020 16:12:15

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7922cb71-3ac8-41be-a169-664553b09635' User entered '26 Sep 2020 11:12'	System	26 Sep 2020 16:12:15
	System	26 Sep 2020 16:12:15

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 12:35'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 2'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:01:59', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7acfc732-1264-4c9a-bd95-e9792afc0761' User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 14:03:38
	System	27 Sep 2020 14:03:38

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:02:05', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7acfc732-1264-4c9a-bd95-e9792afc0761' User entered 'Yes (Y)'	System	27 Sep 2020 14:03:38
	System	27 Sep 2020 14:03:38

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:02:48', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7acfc732-1264-4c9a-bd95-e9792afc0761' User entered '50'	System	27 Sep 2020 14:03:38
	System	27 Sep 2020 14:03:38

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:02:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7acfc732-1264-4c9a-bd95-e9792afc0761' User entered 'Yes (Y)'	System	27 Sep 2020 14:03:38
	System	27 Sep 2020 14:03:38

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7acfc732-1264-4c9a-bd95-e9792afc0761' User entered '40'	System	27 Sep 2020 14:03:38
	System	27 Sep 2020 14:03:38

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:21', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7acfc732-1264-4c9a-bd95-e9792afc0761' User entered 'None (1)'	System	27 Sep 2020 14:03:38
	System	27 Sep 2020 14:03:38

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:35', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7acfc732-1264-4c9a-bd95-e9792afc0761' User entered '27 Sep 2020 09:03'	System	27 Sep 2020 14:03:38
	System	27 Sep 2020 14:03:38

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 3'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:08:58', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b16a5f6-6b49-4cd8-99c1-002f9483103f' User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 16:09:46
	System	28 Sep 2020 16:09:46

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:03', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b16a5f6-6b49-4cd8-99c1-002f9483103f' User entered 'Yes (Y)'	System	28 Sep 2020 16:09:46
	System	28 Sep 2020 16:09:46

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b16a5f6-6b49-4cd8-99c1-002f9483103f' User entered '50'	System	28 Sep 2020 16:09:46
	System	28 Sep 2020 16:09:46

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:17', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b16a5f6-6b49-4cd8-99c1-002f9483103f' User entered 'Yes (Y)'	System	28 Sep 2020 16:09:46
	System	28 Sep 2020 16:09:46

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:29', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b16a5f6-6b49-4cd8-99c1-002f9483103f' User entered '40'	System	28 Sep 2020 16:09:46
	System	28 Sep 2020 16:09:46

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b16a5f6-6b49-4cd8-99c1-002f9483103f' User entered 'None (1)'	System	28 Sep 2020 16:09:46
	System	28 Sep 2020 16:09:46

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b16a5f6-6b49-4cd8-99c1-002f9483103f' User entered '28 Sep 2020 11:09'	System	28 Sep 2020 16:09:46
	System	28 Sep 2020 16:09:46

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 4'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:48:36', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '378e0002-1a06-4b16-b571-23d7e7579e84'	System	29 Sep 2020 12:49:24
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 12:49:24

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:48:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '378e0002-1a06-4b16-b571-23d7e7579e84'	System	29 Sep 2020 12:49:24
User entered 'Yes (Y)'	System	29 Sep 2020 12:49:24

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:48:53', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '378e0002-1a06-4b16-b571-23d7e7579e84' User entered '30'	System	29 Sep 2020 12:49:24
	System	29 Sep 2020 12:49:24

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:48:59', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '378e0002-1a06-4b16-b571-23d7e7579e84'	System	29 Sep 2020 12:49:24
User entered 'Yes (Y)'	System	29 Sep 2020 12:49:24

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:09', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '378e0002-1a06-4b16-b571-23d7e7579e84'	System	29 Sep 2020 12:49:24
User entered '30'	System	29 Sep 2020 12:49:24

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:13', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '378e0002-1a06-4b16-b571-23d7e7579e84'	System	29 Sep 2020 12:49:24
User entered 'None (1)'	System	29 Sep 2020 12:49:24

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:20', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '378e0002-1a06-4b16-b571-23d7e7579e84' User entered '29 Sep 2020 07:49'	System	29 Sep 2020 12:49:24
	System	29 Sep 2020 12:49:24

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 5'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '032d4cbf-8170-43a8-b32e-dc8a17169669' User entered 'None (1)'	System	30 Sep 2020 16:08:01
	System	30 Sep 2020 16:08:01

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:45', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '032d4cbf-8170-43a8-b32e-dc8a17169669' User entered 'No (N)'	System	30 Sep 2020 16:08:01
	System	30 Sep 2020 16:08:01

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '032d4cbf-8170-43a8-b32e-dc8a17169669' User entered 'No (N)'	System	30 Sep 2020 16:08:01
	System	30 Sep 2020 16:08:01

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:56', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '032d4cbf-8170-43a8-b32e-dc8a17169669' User entered 'None (1)'	System	30 Sep 2020 16:08:01
	System	30 Sep 2020 16:08:01

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:07:59', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '032d4cbf-8170-43a8-b32e-dc8a17169669' User entered '30 Sep 2020 11:07'	System	30 Sep 2020 16:08:01
	System	30 Sep 2020 16:08:01

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 6'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:13', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aed033b1-8019-4f7c-a552-2df851266253'	System	01 Oct 2020 13:19:37
User entered 'None (1)'	System	01 Oct 2020 13:19:37

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aed033b1-8019-4f7c-a552-2df851266253' User entered 'No (N)'	System	01 Oct 2020 13:19:37
	System	01 Oct 2020 13:19:37

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aed033b1-8019-4f7c-a552-2df851266253' User entered 'No (N)'	System	01 Oct 2020 13:19:37
	System	01 Oct 2020 13:19:37

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:29', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aed033b1-8019-4f7c-a552-2df851266253'	System	01 Oct 2020 13:19:37
User entered 'None (1)'	System	01 Oct 2020 13:19:37

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:33', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'aed033b1-8019-4f7c-a552-2df851266253' User entered '01 Oct 2020 08:19'	System	01 Oct 2020 13:19:37
	System	01 Oct 2020 13:19:37

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 7'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'bc9ff88b-1186-4aff-9c7f-3a55900ccf4f' User entered 'None (1)'	System	02 Oct 2020 14:36:35
	System	02 Oct 2020 14:36:35

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'bc9ff88b-1186-4aff-9c7f-3a55900ccf4f' User entered 'No (N)'	System	02 Oct 2020 14:36:35
	System	02 Oct 2020 14:36:35

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'bc9ff88b-1186-4aff-9c7f-3a55900ccf4f' User entered 'No (N)'	System	02 Oct 2020 14:36:35
	System	02 Oct 2020 14:36:35

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:29', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'bc9ff88b-1186-4aff-9c7f-3a55900ccf4f' User entered 'None (1)'	System	02 Oct 2020 14:36:35
	System	02 Oct 2020 14:36:35

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:32', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'bc9ff88b-1186-4aff-9c7f-3a55900ccf4f' User entered '02 Oct 2020 09:36'	System	02 Oct 2020 14:36:35
	System	02 Oct 2020 14:36:35

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:54', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered 'None (0)'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:22:56', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered 'None (0)'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:23:00', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered 'None (0)'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:23:03', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered 'None (0)'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:23:05', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered 'None (0)'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:23:08', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered 'None (0)'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:23:15', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered 'No (N)'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FC4BD6F9-4B2B-49C1-95D6-731418AD83CF)', Time: '2020-09-25T09:23:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4a8defec-1d71-4dac-9e62-261b98a28305' User entered '25 Sep 2020 09:23'	System	25 Sep 2020 14:23:23
	System	25 Sep 2020 14:23:23

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 09:10'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 11:40'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered 'None (0)'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:19', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered 'None (0)'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered 'None (0)'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:28', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered 'None (0)'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered 'None (0)'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:35', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered 'None (0)'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:12:47', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered 'No (N)'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-26T11:13:00', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3c65fedf-f68b-449b-8f3d-52d69428f1fa' User entered '26 Sep 2020 11:13'	System	26 Sep 2020 16:13:01
	System	26 Sep 2020 16:13:01

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '25 Sep 2020 12:35'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 2'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:42', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered 'None (0)'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:45', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered 'None (0)'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:49', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered 'None (0)'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered 'None (0)'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered 'None (0)'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:03:57', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered 'None (0)'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:04:02', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered 'No (N)'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-27T09:04:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5c8d9f2d-4809-4df9-a3e1-fdb131327ff3' User entered '27 Sep 2020 09:04'	System	27 Sep 2020 14:04:19
	System	27 Sep 2020 14:04:19

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 3'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:46', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered 'None (0)'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:50', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered 'None (0)'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:09:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered 'None (0)'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:10:12', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered 'None (0)'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:10:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered 'None (0)'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:10:19', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered 'None (0)'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:10:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered 'No (N)'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-28T11:10:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5ae881d4-80cd-45f3-92bd-c31f7c488c0d' User entered '28 Sep 2020 11:10'	System	28 Sep 2020 16:10:29
	System	28 Sep 2020 16:10:29

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 4'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered 'None (0)'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:29', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered 'None (0)'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:31', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered 'None (0)'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:35', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered 'None (0)'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:38', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered 'None (0)'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:49:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered 'None (0)'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:50:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered 'No (N)'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-29T07:50:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'c00a3acf-c342-4fb6-a02a-bdcd3be2b3e0' User entered '29 Sep 2020 07:50'	System	29 Sep 2020 12:50:07
	System	29 Sep 2020 12:50:07

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 5'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered 'None (0)'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:07', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered 'None (0)'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered 'None (0)'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered 'None (0)'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered 'None (0)'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered 'None (0)'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered 'No (N)'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-09-30T11:08:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '025ddf32-d65f-460f-a7ee-a3d542900fe1' User entered '30 Sep 2020 11:08'	System	30 Sep 2020 16:08:28
	System	30 Sep 2020 16:08:28

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 6'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:38', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3' User entered 'None (0)'	System	01 Oct 2020 13:20:09
	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3' User entered 'None (0)'	System	01 Oct 2020 13:20:09
	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:44', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3' User entered 'None (0)'	System	01 Oct 2020 13:20:09
	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:47', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3' User entered 'None (0)'	System	01 Oct 2020 13:20:09
	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:50', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3' User entered 'None (0)'	System	01 Oct 2020 13:20:09
	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:53', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3' User entered 'None (0)'	System	01 Oct 2020 13:20:09
	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:19:57', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3'	System	01 Oct 2020 13:20:09
User entered 'No (N)'	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-01T08:20:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '9a48d501-7ef3-4e11-8385-e8da1a78fca3' User entered '01 Oct 2020 08:20'	System	01 Oct 2020 13:20:09
	System	01 Oct 2020 13:20:09

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	25 Sep 2020 13:52:27
User entered 'Day 7'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:36', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered 'None (0)'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:38', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered 'None (0)'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered 'None (0)'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:43', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered 'None (0)'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:45', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered 'None (0)'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:47', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered 'None (0)'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:51', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered 'No (N)'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-02T09:36:53', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '8d30b33a-595d-4014-afe4-96a77d253fa2' User entered '02 Oct 2020 09:36'	System	02 Oct 2020 14:36:57
	System	02 Oct 2020 14:36:57

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 13:52:27

US3422135

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 13:52:27

US3422135

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:06:57

US3422135

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:29:50
User entered '2 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 17:06:57

US3422135

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:29:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 17:06:57

US3422135

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:29:50
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:06:57

US3422135

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:29:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:06:42

US3422135

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'I'	System	05 Oct 2020 17:06:42

US3422135

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:25:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:44:05

US3422135

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:25:17
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:44:05

US3422135

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:25:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 21:44:05

US3422135

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:25:17
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:44:05

US3422135

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:44:12

US3422135

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'I'	System	09 Oct 2020 21:44:12

US3422135

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 13:40:24

US3422135

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:56
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 13:40:24

US3422135

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 13:40:24

US3422135

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:56
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 13:40:24

US3422135

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:40:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 13:40:33

US3422135

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'I'	System	19 Oct 2020 13:40:33

US3422135

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 17:07:14

US3422135

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:42
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 17:07:14

US3422135

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[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 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Oct 2020 17:07:14

US3422135

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'VISIT3'	System	23 Oct 2020 17:07:14

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered '08:15'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '23 Oct 2020 08:15'	System	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered '098.5' F	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered '090'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'bpm'	System	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered '14'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'breaths/min'	System	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered '133'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:50
User entered '074'	(b) (4), (b) (6)	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'mmHg'	System	23 Oct 2020 17:08:25

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Apr 2021 03:26:38

US3422135

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38

US3422135

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 17:08:41

US3422135

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:59:41
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 17:08:41

US3422135

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:59:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 17:09:01

US3422135

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:59:47
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 17:09:01

US3422135

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:59:47
User entered '08:20'	(b) (4), (b) (6)	23 Oct 2020 17:09:01

US3422135

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered '23 Oct 2020 08:20'	System	23 Oct 2020 17:09:01

US3422135

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:15:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:00:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 17:09:10

US3422135

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:38
User entered 'I'	System	23 Oct 2020 17:09:10

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 64'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-30T12:30:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd667607c-cbf0-4b58-8e09-5c947d14f601' User entered 'No (N)'	System	30 Oct 2020 17:32:07
	System	30 Oct 2020 17:32:07

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-30T12:31:02', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd667607c-cbf0-4b58-8e09-5c947d14f601'	System	30 Oct 2020 17:32:07
User entered 'No (N)'	System	30 Oct 2020 17:32:07

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-10-30T12:32:02', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd667607c-cbf0-4b58-8e09-5c947d14f601' User entered '30 Oct 2020 12:32:02'	System	30 Oct 2020 17:32:07
	System	30 Oct 2020 17:32:07

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 71'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-11-04T00:02:00', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b9f29b25-3c0d-461a-8f44-fbea0ed4e767'	System	04 Nov 2020 06:02:17
User entered 'No (N)'	System	04 Nov 2020 06:02:17

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-11-04T00:02:06', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b9f29b25-3c0d-461a-8f44-fbea0ed4e767'	System	04 Nov 2020 06:02:17
User entered 'No (N)'	System	04 Nov 2020 06:02:17

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-11-04T00:02:13', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b9f29b25-3c0d-461a-8f44-fbea0ed4e767' User entered '04 Nov 2020 00:02:13'	System	04 Nov 2020 06:02:17
	System	04 Nov 2020 06:02:17

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered 'Day 78'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-11-11T20:33:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5d1ba60d-f707-4d46-963f-d0f5d8f32237'	System	12 Nov 2020 02:33:25
User entered 'No (N)'	System	12 Nov 2020 02:33:25

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-11-11T20:33:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5d1ba60d-f707-4d46-963f-d0f5d8f32237'	System	12 Nov 2020 02:33:25
User entered 'No (N)'	System	12 Nov 2020 02:33:25

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-11-11T20:33:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '5d1ba60d-f707-4d46-963f-d0f5d8f32237' User entered '11 Nov 2020 20:33:22'	System	12 Nov 2020 02:33:25
	System	12 Nov 2020 02:33:25

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 14:30:27

US3422135

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:53:46
Data entry locked.	System	28 Aug 2020 14:30:27
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 14:30:27

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-01T12:09:33', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b5ebb616-87d2-4bd9-ab81-8dfac22e9264' User entered 'No (N)'	System	01 Dec 2020 18:09:49
	System	01 Dec 2020 18:09:49

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-01T12:09:43', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b5ebb616-87d2-4bd9-ab81-8dfac22e9264' User entered 'No (N)'	System	01 Dec 2020 18:09:49
	System	01 Dec 2020 18:09:49

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-01T12:09:47', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b5ebb616-87d2-4bd9-ab81-8dfac22e9264' User entered '01 Dec 2020 12:09:47'	System	01 Dec 2020 18:09:49
	System	01 Dec 2020 18:09:49

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-06T00:02:08', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3e9efd1f-cb55-47af-b3aa-f0c8e787190f' User entered 'No (N)'	System	10 Dec 2020 18:53:39

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-10T12:53:24', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3e9efd1f-cb55-47af-b3aa-f0c8e787190f' User entered 'No (N)'	System	10 Dec 2020 18:53:39

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-10T12:53:37', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3e9efd1f-cb55-47af-b3aa-f0c8e787190f' User entered '10 Dec 2020 12:53:37'	System	10 Dec 2020 18:53:39
	System	10 Dec 2020 18:53:39

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-16T10:57:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4cb0105c-3833-4db7-8084-f4fa9e1437b2' User entered 'No (N)'	System	16 Dec 2020 16:57:39
	System	16 Dec 2020 16:57:39

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-16T10:57:24', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4cb0105c-3833-4db7-8084-f4fa9e1437b2' User entered 'No (N)'	System	16 Dec 2020 16:57:39
	System	16 Dec 2020 16:57:39

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-16T10:57:33', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '4cb0105c-3833-4db7-8084-f4fa9e1437b2' User entered '16 Dec 2020 10:57:33'	System	16 Dec 2020 16:57:39
	System	16 Dec 2020 16:57:39

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-22T12:00:54', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '78ecf562-fb7b-4b3a-9183-28e66d308280' User entered 'No (N)'	System	22 Dec 2020 18:01:14
	System	22 Dec 2020 18:01:14

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-22T12:01:03', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '78ecf562-fb7b-4b3a-9183-28e66d308280' User entered 'No (N)'	System	22 Dec 2020 18:01:14
	System	22 Dec 2020 18:01:14

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-22T12:01:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '78ecf562-fb7b-4b3a-9183-28e66d308280' User entered '22 Dec 2020 12:01:10'	System	22 Dec 2020 18:01:14
	System	22 Dec 2020 18:01:14

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-30T11:18:02', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '84432dff-1625-4da5-b351-996c831a6149' User entered 'No (N)'	System	30 Dec 2020 17:18:24
	System	30 Dec 2020 17:18:24

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-30T11:18:13', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '84432dff-1625-4da5-b351-996c831a6149' User entered 'No (N)'	System	30 Dec 2020 17:18:24
	System	30 Dec 2020 17:18:24

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2020-12-30T11:18:21', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '84432dff-1625-4da5-b351-996c831a6149' User entered '30 Dec 2020 11:18:21'	System	30 Dec 2020 17:18:24
	System	30 Dec 2020 17:18:24

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-07T13:09:05', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3d04815e-b5f2-43e5-befc-261812cc4836'	System	07 Jan 2021 19:09:24
User entered 'No (N)'	System	07 Jan 2021 19:09:24

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-07T13:09:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3d04815e-b5f2-43e5-befc-261812cc4836'	System	07 Jan 2021 19:09:24
User entered 'No (N)'	System	07 Jan 2021 19:09:24

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-07T13:09:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3d04815e-b5f2-43e5-befc-261812cc4836' User entered '07 Jan 2021 13:09:14'	System	07 Jan 2021 19:09:24
	System	07 Jan 2021 19:09:24

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-14T10:58:10', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'ab4d74af-fdce-4e5f-9df4-13091ab5a196' User entered 'No (N)'	System	14 Jan 2021 16:58:26
	System	14 Jan 2021 16:58:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-14T10:58:19', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'ab4d74af-fdce-4e5f-9df4-13091ab5a196'	System	14 Jan 2021 16:58:26
User entered 'No (N)'	System	14 Jan 2021 16:58:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-14T10:58:22', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'ab4d74af-fdce-4e5f-9df4-13091ab5a196' User entered '14 Jan 2021 10:58:22'	System	14 Jan 2021 16:58:26
	System	14 Jan 2021 16:58:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-20T16:27:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b47bb4b3-6bc2-4329-acc9-d3f25eb3517c' User entered 'No (N)'	System	20 Jan 2021 22:27:31
	System	20 Jan 2021 22:27:31

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-20T16:27:23', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b47bb4b3-6bc2-4329-acc9-d3f25eb3517c' User entered 'No (N)'	System	20 Jan 2021 22:27:31

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-20T16:27:28', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b47bb4b3-6bc2-4329-acc9-d3f25eb3517c' User entered '20 Jan 2021 16:27:28'	System	20 Jan 2021 22:27:31
	System	20 Jan 2021 22:27:31

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-28T14:34:34', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '02a606dd-adc9-43f9-a339-10d894e10450' User entered 'No (N)'	System	28 Jan 2021 20:35:21
	System	28 Jan 2021 20:35:21

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-28T14:34:40', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '02a606dd-adc9-43f9-a339-10d894e10450' User entered 'No (N)'	System	28 Jan 2021 20:35:21
	System	28 Jan 2021 20:35:21

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-28T14:34:46', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '02a606dd-adc9-43f9-a339-10d894e10450' User entered '28 Jan 2021 14:34:46'	System	28 Jan 2021 20:35:21
	System	28 Jan 2021 20:35:21

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-31T00:01:50', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '35376577-f980-4f10-bf84-4e2222f9f06' User entered 'No (N)'	System	31 Jan 2021 06:02:34
	System	31 Jan 2021 06:02:34

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-31T00:01:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '35376577-f980-4f10-bf84-4e2222f9f06'	System	31 Jan 2021 06:02:34
User entered 'No (N)'	System	31 Jan 2021 06:02:34

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-01-31T00:01:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '35376577-f980-4f10-bf84-4e22222f9f06' User entered '31 Jan 2021 00:01:55'	System	31 Jan 2021 06:02:34

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-07T00:01:27', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '791baff2-5b93-43de-a022-ab2df738c8cc' User entered 'No (N)'	System	07 Feb 2021 06:01:57
	System	07 Feb 2021 06:01:57

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-07T00:01:33', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '791baff2-5b93-43de-a022-ab2df738c8cc'	System	07 Feb 2021 06:01:57
User entered 'No (N)'	System	07 Feb 2021 06:01:57

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-07T00:01:37', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '791baff2-5b93-43de-a022-ab2df738c8cc' User entered '07 Feb 2021 00:01:37'	System	07 Feb 2021 06:01:57
	System	07 Feb 2021 06:01:57

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-16T12:19:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '253893f2-86b3-4c25-bd62-a675b6386431' User entered 'No (N)'	System	16 Feb 2021 18:19:43
	System	16 Feb 2021 18:19:43

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-16T12:19:35', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '253893f2-86b3-4c25-bd62-a675b6386431' User entered 'No (N)'	System	16 Feb 2021 18:19:43
	System	16 Feb 2021 18:19:43

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-16T12:19:41', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '253893f2-86b3-4c25-bd62-a675b6386431' User entered '16 Feb 2021 12:19:41'	System	16 Feb 2021 18:19:43
	System	16 Feb 2021 18:19:43

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-21T11:34:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '803d2ec9-395b-4f78-bacf-a81d0bfc439a' User entered 'No (N)'	System	24 Feb 2021 23:22:01
	System	24 Feb 2021 23:22:01

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-21T11:34:29', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '803d2ec9-395b-4f78-bacf-a81d0bfc439a' User entered 'No (N)'	System	24 Feb 2021 23:22:01
	System	24 Feb 2021 23:22:01

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-21T11:34:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '803d2ec9-395b-4f78-bacf-a81d0bfc439a' User entered '21 Feb 2021 11:34:52'	System	24 Feb 2021 23:22:01
	System	24 Feb 2021 23:22:01

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-28T13:56:45', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b17b629-001a-45ed-a822-4b243e074e03' User entered 'No (N)'	System	28 Feb 2021 19:56:56
	System	28 Feb 2021 19:56:56

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-28T13:56:49', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b17b629-001a-45ed-a822-4b243e074e03'	System	28 Feb 2021 19:56:56
User entered 'No (N)'	System	28 Feb 2021 19:56:56

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-28T13:56:55', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '0b17b629-001a-45ed-a822-4b243e074e03'	System	28 Feb 2021 19:56:56
User entered '28 Feb 2021 13:56:55'	System	28 Feb 2021 19:56:56

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-11T09:55:53', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '2a4d72b9-3e75-4cf8-b473-0820408c575c' User entered 'No (N)'	System	11 Mar 2021 15:56:08
	System	11 Mar 2021 15:56:08

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-11T09:55:58', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '2a4d72b9-3e75-4cf8-b473-0820408c575c' User entered 'No (N)'	System	11 Mar 2021 15:56:08
	System	11 Mar 2021 15:56:08

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-11T09:56:03', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '2a4d72b9-3e75-4cf8-b473-0820408c575c' User entered '11 Mar 2021 09:56:03'	System	11 Mar 2021 15:56:08
	System	11 Mar 2021 15:56:08

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-17T12:00:16', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e8026aa5-c7a5-4623-98be-ba5df3ab7ca2'	System	17 Mar 2021 17:00:38
User entered 'No (N)'	System	17 Mar 2021 17:00:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-17T12:00:20', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e8026aa5-c7a5-4623-98be-ba5df3ab7ca2'	System	17 Mar 2021 17:00:38
User entered 'No (N)'	System	17 Mar 2021 17:00:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-17T12:00:24', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e8026aa5-c7a5-4623-98be-ba5df3ab7ca2' User entered '17 Mar 2021 12:00:24'	System	17 Mar 2021 17:00:38
	System	17 Mar 2021 17:00:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-23T12:00:58', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7637573d-d375-494a-8f07-0da88750b4a2'	System	23 Mar 2021 17:02:26
User entered 'No (N)'	System	23 Mar 2021 17:02:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-23T12:01:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7637573d-d375-494a-8f07-0da88750b4a2'	System	23 Mar 2021 17:02:26
User entered 'No (N)'	System	23 Mar 2021 17:02:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-23T12:01:19', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7637573d-d375-494a-8f07-0da88750b4a2'	System	23 Mar 2021 17:02:26
User entered '23 Mar 2021 12:01:19'	System	23 Mar 2021 17:02:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-30T13:46:13', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b0e78d49-3221-48bd-b1e5-c8e9bfa2fd3b'	System	30 Mar 2021 18:46:26
User entered 'No (N)'	System	30 Mar 2021 18:46:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-30T13:46:17', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b0e78d49-3221-48bd-b1e5-c8e9bfa2fd3b' User entered 'No (N)'	System	30 Mar 2021 18:46:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-03-30T13:46:21', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'b0e78d49-3221-48bd-b1e5-c8e9bfa2fd3b' User entered '30 Mar 2021 13:46:21'	System	30 Mar 2021 18:46:26
	System	30 Mar 2021 18:46:26

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-04T08:20:11', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3cfc9307-dfd7-4f93-a6fa-7495b0435b3c' User entered 'No (N)'	System	04 Apr 2021 13:20:22
	System	04 Apr 2021 13:20:22

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-04T08:20:14', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3cfc9307-dfd7-4f93-a6fa-7495b0435b3c' User entered 'No (N)'	System	04 Apr 2021 13:20:22
	System	04 Apr 2021 13:20:22

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-04T08:20:18', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '3cfc9307-dfd7-4f93-a6fa-7495b0435b3c' User entered '04 Apr 2021 08:20:18'	System	04 Apr 2021 13:20:22
	System	04 Apr 2021 13:20:22

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-11T07:54:56', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd5f470ed-94f9-4e92-ae4d-48afc7cf1ae2' User entered 'No (N)'	System	11 Apr 2021 12:55:38
	System	11 Apr 2021 12:55:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-11T07:55:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd5f470ed-94f9-4e92-ae4d-48afc7cf1ae2'	System	11 Apr 2021 12:55:38
User entered 'No (N)'	System	11 Apr 2021 12:55:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-11T07:55:04', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd5f470ed-94f9-4e92-ae4d-48afc7cf1ae2'	System	11 Apr 2021 12:55:38
User entered '11 Apr 2021 07:55:04'	System	11 Apr 2021 12:55:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-18T07:06:52', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '70864c4c-8743-4bd5-9fb8-6af4af75d9a4'	System	24 Apr 2021 14:10:28
User entered 'No (N)'	System	24 Apr 2021 14:10:28

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-18T07:06:57', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '70864c4c-8743-4bd5-9fb8-6af4af75d9a4'	System	24 Apr 2021 14:10:28
User entered 'No (N)'	System	24 Apr 2021 14:10:28

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-18T07:07:17', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '70864c4c-8743-4bd5-9fb8-6af4af75d9a4'	System	24 Apr 2021 14:10:28
User entered '18 Apr 2021 07:07:17'	System	24 Apr 2021 14:10:28

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-25T10:34:30', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7274e10b-3c91-4d8a-b040-79986e3b77fa' User entered 'No (N)'	System	25 Apr 2021 15:34:45
	System	25 Apr 2021 15:34:45

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-25T10:34:35', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7274e10b-3c91-4d8a-b040-79986e3b77fa' User entered 'No (N)'	System	25 Apr 2021 15:34:45
	System	25 Apr 2021 15:34:45

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-04-25T10:34:43', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: '7274e10b-3c91-4d8a-b040-79986e3b77fa' User entered '25 Apr 2021 10:34:43'	System	25 Apr 2021 15:34:45
	System	25 Apr 2021 15:34:45

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-05-02T00:01:26', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd2179c4f-a67d-4c08-95e1-1d15b5491943'	System	02 May 2021 05:01:38
User entered 'No (N)'	System	02 May 2021 05:01:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

Have you been exposed to someone with 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 (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-05-02T00:01:29', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd2179c4f-a67d-4c08-95e1-1d15b5491943'	System	02 May 2021 05:01:38
User entered 'No (N)'	System	02 May 2021 05:01:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-05-02T00:01:33', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'd2179c4f-a67d-4c08-95e1-1d15b5491943'	System	02 May 2021 05:01:38
User entered '02 May 2021 00:01:33'	System	02 May 2021 05:01:38

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:38:55

US3422135

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:55
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:38:55

US3422135

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:33:17

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)	26 Apr 2021 02:41:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-28T13:57:01', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e6044b7f-7e94-4b78-8621-dd8f6975013a'	System	28 Feb 2021 19:57:10
User entered 'No (N)'	System	28 Feb 2021 19:57:10

US3422135

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:33:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 02:41:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (588FEA8E-6318-4F34-B39D-3B008FC724D2)', Time: '2021-02-28T13:57:07', User OID: 'PatientReportedOutcome (US3422135)', ODM File OID: 'e6044b7f-7e94-4b78-8621-dd8f6975013a' User entered '28 Feb 2021 13:57:07'	System	28 Feb 2021 19:57:10
	System	28 Feb 2021 19:57:10

US3422135

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:50:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:46:07
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	23 Nov 2020 16:46:34

US3422135

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:50:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:46:07
User entered '20 Nov 2020'	Cindy Trimmer (b) (4)	23 Nov 2020 16:46:34

US3422135

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:50:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:46:07
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4) (b) (4)	23 Nov 2020 16:46:34

US3422135

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:50:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:46:07
User entered empty.	Cindy Trimmer (b) (4)	23 Nov 2020 16:46:34

US3422135

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:50:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:45:59
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	23 Nov 2020 16:46:38

US3422135

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:26:30
User entered 'I'	System	23 Nov 2020 16:46:38

US3422135

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:45:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 18:50:52

US3422135

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:45:51
User entered '22 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 18:50:52

US3422135

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:45:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 18:50:52

US3422135

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:45:51
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 18:50:52

US3422135

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:45:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 18:51:01

US3422135

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User entered 'I'	System	22 Dec 2020 18:51:01

US3422135

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:56:11
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	22 Jan 2021 16:44:36

US3422135

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:56:11
User entered '22 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	22 Jan 2021 16:44:36

US3422135

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:56:11
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4) (b) (4)	22 Jan 2021 16:44:36

US3422135

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:56:11
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	22 Jan 2021 16:44:36

US3422135

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:56:15
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	22 Jan 2021 16:44:40

US3422135

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User entered 'I'	System	22 Jan 2021 16:44:40

US3422135

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:56:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:28:59

US3422135

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:56:53
User entered '22 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:28:59

US3422135

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:56:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 18:28:59

US3422135

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:56:53
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:28:59

US3422135

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:57:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:29:06

US3422135

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:55:09
User entered 'I'	System	22 Feb 2021 18:29:06

US3422135

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:42

US3422135

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:42

US3422135

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:42

US3422135

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 18:34:42

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:33:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:34:53

US3422135

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:35:00

US3422135

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:33:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:35:00

US3422135

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:35:44

US3422135

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:35:44

US3422135

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered '11:15'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:35:44

US3422135

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 11:15'	System	30 Mar 2021 18:35:44

US3422135

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:34:26

US3422135

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:34:26

US3422135

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:36:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 15:23:27

US3422135

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:36:45
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:23:27

US3422135

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:23:27

US3422135

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:33:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:23:27

US3422135

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:36:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 15:23:35

US3422135

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 15:23:35

US3422135

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

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:14
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:28:43

US3422135

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

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:14
User entered '11 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:28:43

US3422135

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

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[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 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:14
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:28:43

US3422135

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

Form: Visit Date

Generated On: 09 Jun 2021 17:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 20:28:43

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:47
User entered '06 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:58:02
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:49:24
User entered '0'	(b) (4) Wendy Winn (b) (4)	08 Apr 2021 19:33:47
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:50:37

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:47
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:58:04
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:24:13
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:49:24
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Reviewed and Updated' (Site from DM).	(b) (4)	
	Wendy Winn (b) (4)	08 Apr 2021 19:34:10
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Wendy Winn (b) (4)	08 Apr 2021 19:33:47
	(b) (4)	
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:41:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:50:37

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:47
User entered '11 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:47
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 13:12:39
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 13:12:39
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:20:47
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User entered empty.	System	11 Jan 2021 20:29:08

US3422135

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

Form: Unblinding

Generated On: 09 Jun 2021 17:33:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User entered empty.	System	11 Jan 2021 20:29:08

US3422135

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:22:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:28

US3422135

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:22:01
User entered '11 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:28

US3422135

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:22:01
User entered '12:18'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:28

US3422135

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User entered '11 Jan 2021 12:18'	System	11 Jan 2021 20:29:28

US3422135

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:22:17
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:47

US3422135

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:22:17
User entered '11 Jan 2021'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:47

US3422135

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:22:17
User entered '12:15'	Cindy Trimmer (b) (4) (b) (4)	11 Jan 2021 20:29:47

US3422135

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:33:17

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:20:16
User entered '11 Jan 2021 12:15'	System	11 Jan 2021 20:29:47

US3422135

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:33:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:21
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:38:14
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	09 Oct 2020 21:11:42

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:12:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:07:08
User entered	System	12 Oct 2020 15:05:43
'USA-US082-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 15:05:43

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 04:18:36
Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 21:12:58 05 Nov 2020 14:40:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:38:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:38:45
Data point term sent to Coder	System	29 Oct 2020 21:37:57
User entered 'SPINAL STENOSIS' reason for change: Data Entry Error	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:37:10
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:54:54
User closed query 'PV Query: Please record the medical condition or complication, which prolonged the hospitalization, as the event term (i.e. increased blood flow to surgical site or complication of lumbar spine fusion).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:23:35
Data point term sent to Coder	System	22 Oct 2020 18:48:09
Query 'PV Query: Please record the medical condition or complication, which prolonged the hospitalization, as the event term (i.e. increased blood flow to surgical site or complication of lumbar spine fusion).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 18:47:17

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 18:47:11
User entered 'Laminectomy with Posterolateral fusion' reason for change: Data Entry Error		22 Oct 2020 18:47:11
User opened query 'PV Query: Please record the medical condition or complication, which prolonged the hospitalization, as the event term (i.e. increased blood flow to surgical site or complication of lumbar spine fusion).' (Site from Safety).		20 Oct 2020 16:00:36
Query 'PV Query: Please consider updating event term to include disease progression of sciatica.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:56:50
User opened query 'PV Query: Please consider updating event term to include disease progression of sciatica.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 13:17:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Hospitalisation, LLT: Hospitalization - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:43:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:43:27
Data point term sent to Coder	System	09 Oct 2020 21:41:32
User entered 'prolonged hospitalization'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:13:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	11 Nov 2020 21:13:09
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:05
DataPoint Verified.		11 Nov 2020 21:13:02
User entered 'No (N)'		09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:13:07
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:13:11
User entered '06 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:13:13
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:13:14
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:13:16
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	12 Oct 2020 19:49:17
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	12 Oct 2020 19:49:17
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	09 Oct 2020 21:41:00
User entered '08 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:13:18
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:13:21
	(b) (4), (b) (6)	23 Oct 2020 19:22:45
User closed query 'PV Query: As the subject was hospitalized, please consider updating severity to grade 4.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 18:45:14
Query 'PV Query: As the subject was hospitalized, please consider updating severity to grade 4.' answered with 'correct as entered' (Site from Safety).		
User opened query 'PV Query: As the subject was hospitalized, please consider updating severity to grade 4.' (Site from Safety).		19 Oct 2020 13:17:48
User entered 'Grade 3/Severe (Grade 3/Severe)'		09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:26
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:27
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:14:29
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Oct 2020 19:50:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	12 Oct 2020 19:50:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Oct 2020 21:41:00
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:31
User entered '06 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:32
User entered '08 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:14:34
User entered 'No (N)' reason for change: Data Entry Error	Cindy Trimmer (b) (4)	12 Oct 2020 19:50:40
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:14:36
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:37
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:38
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:40
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:42
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:43
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:14:44
User closed query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:22:51
Query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 18:47:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		22 Oct 2020 18:47:11
User opened query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		19 Oct 2020 13:17:20
User entered 'None (NONE)'		09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

None

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:12:21
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:12:23
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:12:24
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:41:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Cindy Trimmer (b) (4) (b) (4)	12 Oct 2020 19:49:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:14:48
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:30:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:14:51
User closed query 'PV query: Please clarify the report of "increased blood flow to the area" following lumbar fusion.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 02:13:25
Query 'PV query: Please clarify the report of "increased blood flow to the area" following lumbar fusion.' answered with 'patient report not noted in medical records' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:41:44
User opened query 'PV query: Please clarify the report of "increased blood flow to the area" following lumbar fusion.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:43:53
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)	28 Oct 2020 16:49:51
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 'done' (Site from Safety).	Naomi Kown (b) (4)	27 Oct 2020 18:26:46
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)	23 Oct 2020 19:23:50
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)	23 Oct 2020 19:23:47
User closed query 'PV query: Please clarify the report of "increased blood flow to the area" following lumbar fusion.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:23:09
Query 'PV query: Please clarify the report of "increased blood flow to the area" following lumbar fusion.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 18:50:34

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

[Narrative](#)

Audit	User	Time (GMT)
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 'will provide' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 18:50:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'will provide' (Site from Safety).		22 Oct 2020 18:50:19
User entered 'Patient was admitted for planned procedure (lumbar spine L4-L5 fusion) due to sciatica that started ago. Inpatient for 48 hours.' reason for change: Data Entry Error		22 Oct 2020 18:47:11
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).		19 Oct 2020 13:18:08
User opened query 'PV query: Please clarify the report of "increased blood flow to the area" following lumbar fusion.' (Site from Safety).		19 Oct 2020 13:18:01
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).		19 Oct 2020 13:17:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		19 Oct 2020 13:17:00
User entered 'patient was admitted for planned procedure (lumbar spine L4-L5 fusion) due to sciatica that started 15 months ago. Due to increased blood flow to the area, the surgery team kept him overnight in the hospital for additional monitoring.'		09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 21:41:00

US3422135

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:33:17

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

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 19:50:40

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:33:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:01:46
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:33:40

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:40
Data point term sent to Coder	System	13 Nov 2020 21:43:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:02:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:37:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:37:45
Data point term sent to Coder	System	28 Aug 2020 15:36:34
User entered 'levothyroxine'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:35:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:02:09
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:02:10
User entered 'hypothyroidism'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:02:12
User entered '125'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Source indicates unit as mcg. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:45:08
Query 'Source indicates unit as mcg. Please confirm and update as needed.' answered with 'mcg/ug is used interchangeably' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:45:01
User opened query 'Source indicates unit as mcg. Please confirm and update as needed.' (Site from CRA).	Naomi Kown (b) (4)	22 Sep 2020 14:57:12
User closed query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4)	
Query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' answered with 'Dose updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:02:38
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:07:01
User opened query 'Per CDM: 'Dose unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:18:14
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 18:17:53
	(b) (4), (b) (6)	09 Sep 2020 16:40:40
	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:02:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:17:53
User entered 'mcg'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:02:42
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:02:45
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:02:49
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:02:51
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 1984' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:48:58
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:48:58
		17 Sep 2020 16:02:56
User entered '30 Jun 1984'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:02:58
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:00
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:03
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:06
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:35:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:35:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:35:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:35:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:40
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:03:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:37:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:37:45
Data point term sent to Coder	System	28 Aug 2020 15:36:34
User entered 'Simvastatin'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:36:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:03:16
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:03:21
User entered 'hypercholesterolemia'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:03:24
User entered '40'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:25
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:28
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:31
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:32
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:03:35
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:37
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 1994' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:51:34
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:51:34
		17 Sep 2020 16:03:39
User entered '30 Jun 1994'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:42
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:44
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:03:47
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:03:49
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:36:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:36:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:36:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:36:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:39
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:03:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:38:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:38:50
Data point term sent to Coder	System	28 Aug 2020 15:37:36
User entered 'Aspirin'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:37:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:04:02
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:04:04
User entered 'General health'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:04:06
User entered '81'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:04:09
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:04:18
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:05:12
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:05:20
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:05:27
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 2002' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:51:55
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:51:55
		17 Sep 2020 16:05:30
User entered '30 Jun 2002'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:05:31
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:05:34
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:05:36
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:05:38
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:37:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:37:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:37:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:37:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:59:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:59:46
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:05:46
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) (b) (4)	28 Aug 2020 15:39:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:39:36
Data point term sent to Coder	System	28 Aug 2020 15:38:37
User entered 'Metoprolol ER'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:38:12

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:06:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:06:25
User entered 'hypertension'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:28
User entered '25'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:29
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:31
	(b) (4)	
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:32
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:06:34
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:06:35
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:36
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 2003' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:52:21
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:52:21
		17 Sep 2020 16:06:39
User entered '30 Jun 2003'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:41
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:43
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:45
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:48
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:12
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:38:12

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:38:12

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:38:12

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:40
Data point term sent to Coder	System	13 Nov 2020 21:43:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:06:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:40:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:40:39
Data point term sent to Coder	System	28 Aug 2020 15:39:40
User entered 'Losartan'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:38:56

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:06:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:06:57
User entered 'hypertension'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:00
User entered '25'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:01
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:03
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:04
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:06
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:08
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:09
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 2016' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:52:43
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:52:43
		17 Sep 2020 16:07:10
User entered '30 Jun 2016'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:12
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:13
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:14
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:19
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:38:56
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:38:56

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:38:56

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:38:56

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:42
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:07:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:40:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:40:39
Data point term sent to Coder	System	28 Aug 2020 15:39:40
User entered 'Metformin'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:39:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:07:26
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:07:27
User entered 'Type II Diabetes'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:30
User entered '500'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:32
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:34
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:35
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:37
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:07:39
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:43
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of TYPE II DIABETES. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:52:39
Query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of TYPE II DIABETES. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:41:28
DataPoint Un-verified.	Naomi Kown (b) (4)	27 Oct 2020 18:13:45
User entered 'un UNK 2007' reason for change: New Information	(b) (4)	
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of TYPE II DIABETES. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 18:53:20
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:53:20
User entered '30 Jun 2007'	(b) (4), (b) (6)	25 Sep 2020 05:00:43
	(b) (4), (b) (6)	17 Sep 2020 16:07:45
	(b) (4)	
	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:50
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:07:57
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:08:01
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:39:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:39:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:39:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:39:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:41
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:08:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:27:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:27:39
Data point term sent to Coder	System	28 Aug 2020 15:40:41
User entered 'Buspirone'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:40:24

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:08:58
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:00
User entered 'General anxiety'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:05
User entered '7.5'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:06
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:08
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:14
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:15
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:09:27
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:30
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 2018' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:54:23
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:54:23
		17 Sep 2020 16:09:37
User entered '30 Jun 2018'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:40
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:42
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:09:45
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:09:46
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:40:24
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:40:24

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:40:24

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:40:24

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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) (b) (4)	13 Nov 2020 21:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:59:47
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:10:03
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) (b) (4)	29 Aug 2020 07:30:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 07:30:34
Data point term sent to Coder	System	28 Aug 2020 15:41:42
User entered 'Multivitamin'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:41:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:05
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:20
User entered 'General health'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:27
User entered 'I'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:29
User entered 'tablet (TABLET)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:31
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:10:33
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:36
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:10:39
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:43
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 1979' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:54:55
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:54:55
		17 Sep 2020 16:10:45
User entered '30 Jun 1979'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:48
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:50
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:52
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:10:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:41:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:41:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:41:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:41:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 21:44:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:41
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:11:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:43:49
Data point term sent to Coder	System	28 Aug 2020 15:42:45
User entered 'Trulicity'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:11:03
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:05
User entered 'Type II diabetes'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:08
User entered '1.5'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:10
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:12
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:11:13
User entered 'every week (QS)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:15
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:19
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data no required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		16 Oct 2020 18:55:18
User entered 'un UNK 2016' reason for change: New Information		16 Oct 2020 18:55:18
DataPoint Verified.		17 Sep 2020 16:11:22
User entered '30 Jun 2016'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:11:25
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:11:27
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:12:11
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:12:14
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:42:17
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:42:17

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:42:17

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '803 (803)'	System	28 Aug 2020 15:42:17

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:59:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:59:46
Data point term sent to Coder	System	13 Nov 2020 21:43:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:12:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 07:28:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 07:28:33
Data point term sent to Coder	System	28 Aug 2020 15:43:51
User entered 'Naproxen'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:43:14

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:12:33
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
Query 'Per DM CLR: Please review and update the CM indication to include the specific location of the SCIATICA (i.e.: Right, Left or Bilateral). Review and update the CM page and ensure reconciliation with the AE/MH pages so there is a match as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User opened query 'Per DM CLR: Please review and update the CM indication to include the specific location of the SCIATICA (i.e.: Right, Left or Bilateral). Review and update the CM page and ensure reconciliation with the AE/MH pages so there is a match as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:04:46
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 14:01:51
User entered 'Sciatica'	(b) (4), (b) (6)	17 Sep 2020 16:12:35
	(b) (4)	28 Aug 2020 15:43:14

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.		11 Nov 2020 16:49:37
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).		06 Nov 2020 13:42:38
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.' answered with 'corrected' (Site from DM).	Naomi Kown (b) (4)	27 Oct 2020 18:16:20
DataPoint Un-verified.	(b) (4)	
User entered '220' reason for change: Data Entry Error	Naomi Kown (b) (4)	27 Oct 2020 18:15:45
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 14:02:29
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:12:41
User entered '1-2'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.		11 Nov 2020 16:49:39
DataPoint Un-verified.	Naomi Kown (b) (4)	27 Oct 2020 18:15:45
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	27 Oct 2020 18:15:45
DataPoint Verified.	Naomi Kown (b) (4)	17 Sep 2020 16:12:44
	(b) (4), (b) (6)	
User entered 'tablet (TABLET)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:12:46
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:12:49
User entered 'as needed (PRN)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:12:51
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:12:52
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:12:54
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 2019' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:55:56
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:55:56
		17 Sep 2020 16:12:56
User entered '30 Jun 2019'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:12:58
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:00
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:01
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:02
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:14
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	28 Aug 2020 15:43:14

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	28 Aug 2020 15:43:14

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	28 Aug 2020 15:43:14

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 21:44:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:43
Data point term sent to Coder	System	13 Nov 2020 21:43:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:44:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:44:37
Data point term sent to Coder	System	28 Aug 2020 15:43:55
User entered 'Singular'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:10
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:15
User entered 'seasonal allergies'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:17
User entered '10'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:22
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:26
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:27
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:02:24
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:31
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:32
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		16 Oct 2020 18:56:24
User entered 'un UNK 2018' reason for change: New Information		16 Oct 2020 18:56:24
DataPoint Verified.		17 Sep 2020 16:13:35
User entered '30 Jun 2018'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:37
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:13:39
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:42
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:13:45
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:43:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:43:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:43:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:43:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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 D 3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 21:59:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:59:46
Data point term sent to Coder	System	13 Nov 2020 21:43:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:07
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 D 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:45:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 15:45:38
Data point term sent to Coder	System	28 Aug 2020 15:44:57
User entered 'Vitamin D-3'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:09
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:12
User entered 'General health'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:15
User entered '2000'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:16
User entered 'IU (IU)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:20
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:21
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:23
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:25
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:26
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		16 Oct 2020 18:56:46
User entered 'un UNK 2015' reason for change: New Information		16 Oct 2020 18:56:46
DataPoint Verified.		17 Sep 2020 16:14:28
User entered '30 Jun 2015'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:32
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:35
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:14:37
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:38
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:44:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:44:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered 'I'	System	28 Aug 2020 15:44:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	28 Aug 2020 15:44:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Feb 2021 19:36:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 19:36:04
Data point term sent to Coder	System	03 Feb 2021 18:37:25
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	03 Feb 2021 18:36:49
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'not relevant to the study. thank you.' (Site from System).	Anna Gallion (b) (4)	03 Feb 2021 18:36:49
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)	03 Feb 2021 10:20:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:42
Data point term sent to Coder	System	13 Nov 2020 21:43:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:01:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:01:48
Data point term sent to Coder	System	22 Sep 2020 15:00:27
Coding entries removed.	Naomi Kown (b) (4) (b) (4)	22 Sep 2020 14:59:49
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:46:42
Data point term sent to Coder	System	28 Aug 2020 15:46:00
User entered 'Flonase'	Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:45:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:14:54
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:15:03
User entered 'seasonal allergies'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:15:05
User entered 'I'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.		17 Sep 2020 16:15:53
DataPoint Un-verified.		17 Sep 2020 16:15:22
DataPoint Verified.		17 Sep 2020 16:15:20
User entered 'Other (OTHER)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:15:56
User entered 'inhaled'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:15:57
User entered 'as needed (PRN)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:15:59
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Subject indicates route as INH. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:45:36
Query 'Subject indicates route as INH. Please confirm and update as needed.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:45:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Naomi Kown (b) (4)	22 Sep 2020 15:00:03
User opened query 'Subject indicates route as INH. Please confirm and update as needed.' (Site from CRA).	(b) (4)	
User entered 'Nasal (NASAL)'	Naomi Kown (b) (4)	22 Sep 2020 14:59:49
	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 16:16:37
	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:16:39
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'un UNK 2018' reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 18:57:38
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 18:57:38
		17 Sep 2020 16:16:43
User entered '30 Jun 2018'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:16:45
User entered '0'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:16:46
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 16:16:48
User entered empty.	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	17 Sep 2020 16:16:50
User entered 'No (N)'	Cindy Trimmer (b) (4)	28 Aug 2020 15:45:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	28 Aug 2020 15:45:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	28 Aug 2020 15:45:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	28 Aug 2020 15:45:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 18:11:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:11:55
Data point term sent to Coder	System	07 Dec 2020 17:55:38
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 17:55:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 22:15:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 22:15:48
Data point term sent to Coder	System	13 Nov 2020 21:43:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Please confirm this medication and dosage. Per medical records, discharge medication seems to be Acetaminophen/Hydrocodone 7.5 mg/325 mg) to be taken 1 tab every 6 hours. Please advise.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:37:47

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'Please confirm this medication and dosage. Per medical records, discharge medication seems to be Acetaminophen/Hydrocodone 7.5 mg/325 mg) to be taken 1 tab every 6 hours. Please advise.' answered with 'patient instructed to use tylenol if possible, but could use acetaminophen/hydrocodone if needed.' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:09:13
User opened query 'Please confirm this medication and dosage. Per medical records, discharge medication seems to be Acetaminophen/Hydrocodone 7.5 mg/325 mg) to be taken 1 tab every 6 hours. Please advise.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:00:40
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:31:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Oct 2020 21:31:31
Data point term sent to Coder	System	09 Oct 2020 21:30:22
User entered 'tylenol'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Verified.		29 Oct 2020 21:50:09
User entered 'No (N)'		09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:20:14
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' answered with 'clarified' (Site from DM).	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 17:55:37
DataPoint Un-verified.	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 17:55:26
User entered 'POST OPERATIVE PAIN' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 17:55:26
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 22:20:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:11
User entered 'post operative care'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:12
User entered '1000'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:13
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:15
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
DataPoint Un-verified.	Clarence Creech (b) (4)	11 Nov 2020 22:10:38
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4)	
User entered 'as needed (PRN)' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:10:38
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' canceled (Site from DM).	(b) (4)	
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:58:29
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:17
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:47:04
User entered 'other (OTHER)'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Please confirm if 8 hours or 6 hours is correct per medical records. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:37:57
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
DataPoint Un-verified.	Clarence Creech (b) (4)	11 Nov 2020 22:10:38
User entered empty; reason for change Data Entry Error	(b) (4)	
Query 'Please confirm if 8 hours or 6 hours is correct per medical records. ' answered with 'Confirmed q8h' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:10:38
Query 'Please confirm if 8 hours or 6 hours is correct per medical records. ' answered with 'Confirmed q8h' (Site from CRA).	(b) (4)	11 Nov 2020 22:08:54
User opened query 'Please confirm if 8 hours or 6 hours is correct per medical records. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:01:18
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:19
User entered 'every 8 hours'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:22
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Please confirm if this should be 08Oct2020, date of discharge. if so, please update.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
Query 'Please confirm if this should be 08Oct2020, date of discharge. if so, please update.' answered with 'It should be october 8; volunteer initially reported october 6; source updated.' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:12:35
DataPoint Un-verified.	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:12:17
User opened query 'Please confirm if this should be 08Oct2020, date of discharge. if so, please update.' (Site from CRA).	(b) (4)	
User opened query 'Please confirm if this should be 08Oct2020, date of discharge. if so, please update.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:19:47
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:23
User entered '06 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:25
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Naomi Kown (b) (4)	24 Nov 2020 20:25:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Naomi Kown (b) (4)	24 Nov 2020 20:25:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Please confirm, is the subject currently taking this medication, or is there a stop date to add to source worksheets and EDC. Please update/clarify. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:09:02
Query 'Please confirm, is the subject currently taking this medication, or is there a stop date to add to source worksheets and EDC. Please update/clarify. ' answered with 'No stop date; he continues to take as needed' (Site from CRA).	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:10:23
User opened query 'Please confirm, is the subject currently taking this medication, or is there a stop date to add to source worksheets and EDC. Please update/clarify. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:52:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Naomi Kown (b) (4)	24 Nov 2020 20:25:07
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4) Naomi Kown (b) (4)	24 Nov 2020 20:25:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:28
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Please confirm if this should be no. As this event was for an SAE. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:38:29
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
Query 'Please confirm if this should be no. As this event was for an SAE. ' answered with 'updated in source as well' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:12:43
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:10:38
User opened query 'Please confirm if this should be no. As this event was for an SAE. ' (Site from CRA).	(b) (4)	
User opened query 'Please confirm if this should be no. As this event was for an SAE. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:55:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:50:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	09 Oct 2020 21:29:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:01:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:01:51
Data point term sent to Coder Coding entries removed.	System Anna Gallion (b) (4)	07 Dec 2020 17:57:40 07 Dec 2020 17:56:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:42
Data point term sent to Coder	System	13 Nov 2020 21:43:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 23:34:37

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder DataPoint Un-verified.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:34:37
	System	11 Nov 2020 22:13:31
	Clarence Creech (b) (4)	11 Nov 2020 22:13:29
	(b) (4)	
Coding entries removed.	Clarence Creech (b) (4)	11 Nov 2020 22:13:29
	(b) (4)	
User entered 'CYCLOBENZAPRINE' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:13:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 21:49:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:55:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:55:20
Data point term sent to Coder	System	09 Oct 2020 21:32:23
User entered 'cyclobenzapine'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 02:28:28
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' answered with 'clarified' (Site from DM).	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 17:56:50
DataPoint Un-verified.	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 17:56:43
User entered 'POST-OPERATIVE CARE pain and muscle spasm' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 17:56:43
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:23:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Verified.		29 Oct 2020 21:49:29
User entered 'post-operative care'		09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:30
User entered '10'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:32
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:38
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:51:47
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'complete' (Site from DM).	Naomi Kown (b) (4) (b) (4)	24 Nov 2020 19:32:59
DataPoint Un-verified.	Naomi Kown (b) (4) (b) (4)	24 Nov 2020 19:32:43
User entered 'three times daily (TID)' reason for change: Data Entry Error	Naomi Kown (b) (4) (b) (4)	24 Nov 2020 19:32:43
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:04:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
Query 'Please confirm, it appears on the medication log from the surgical procedure this was prescribed at TID. If confirmed, should this be updated? If so, please update or clarify otherwise. ' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:42:59
User opened query 'Please confirm, it appears on the medication log from the surgical procedure this was prescribed at TID. If confirmed, should this be updated? If so, please update or clarify otherwise. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:26:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' canceled (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:58:44
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM). User entered 'other (OTHER)'	(b) (4), (b) (6)	29 Oct 2020 21:49:40
	(b) (4), (b) (6)	16 Oct 2020 13:47:12
	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Naomi Kown (b) (4)	24 Nov 2020 19:32:43
User entered empty; reason for change Data Entry Error	(b) (4) Naomi Kown (b) (4)	24 Nov 2020 19:32:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:42
User entered 'every 8 hours'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:45
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:46
User entered '06 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:48
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Naomi Kown (b) (4)	24 Nov 2020 20:24:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Naomi Kown (b) (4)	24 Nov 2020 20:24:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Please confirm this medication is still ongoing. If not, please update.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:38:45
Query 'Please confirm this medication is still ongoing. If not, please update.' answered with 'Ongoing per participant report' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:13:38
User opened query 'Please confirm this medication is still ongoing. If not, please update.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:25:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Naomi Kown (b) (4)	24 Nov 2020 20:24:35
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4) Naomi Kown (b) (4)	24 Nov 2020 20:24:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:51
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User closed query 'Please confirm, if this should be "no" as this was for SAE.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:38:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
Query 'Please confirm, if this should be "no" as this was for SAE.' answered with 'updated' (Site from CRA).	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:13:55
DataPoint Un-verified.	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:13:51
User entered 'No (N)' reason for change: Data Entry Error	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:13:51
User opened query 'Please confirm, if this should be "no" as this was for SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:56:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:31:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User entered '3'	System	24 Nov 2020 19:32:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User entered '1'	System	24 Nov 2020 19:32:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:10
User entered '804 (804)'	System	24 Nov 2020 19:32:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	09 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 16:50:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 16:50:03
Data point term sent to Coder	System	07 Dec 2020 18:00:42
Coding entries removed.	Anna Gallion (b) (4)	07 Dec 2020 18:00:03
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:14:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:50
Data point term sent to Coder	System	13 Nov 2020 21:43:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:14:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:55
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: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:37:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:37:22
Data point term sent to Coder	System	09 Oct 2020 21:35:25
User entered 'medrol dose pack'	(b) (4), (b) (6)	09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:14:11
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:19
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		11 Nov 2020 17:14:35
DataPoint Verified.		29 Oct 2020 21:53:56
User entered 'No (N)'		09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 02:20:24
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate. ' answered with 'clarified' (Site from DM).	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 18:02:00
DataPoint Un-verified.	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 18:00:03
User entered 'POST-OPERATIVE CARE, pain and inflammation' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	07 Dec 2020 18:00:03
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:39:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:14:10
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data no required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:21
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		11 Nov 2020 17:14:37
DataPoint Verified.		29 Oct 2020 21:53:57
User entered 'post-operative care'		09 Oct 2020 21:34:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:14:07
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
User closed query 'Please confirm how long 4 mg was taken, as a medrol dose pack is typically tapered for a set amount of days with a set end date/duration. ' (Site from CRA).		13 Nov 2020 21:39:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
Query 'Please confirm how long 4 mg was taken, as a medrol dose pack is typically tapered for a set amount of days with a set end date/duration. ' answered with 'Updated in source' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:17:33
DataPoint Un-verified.	(b) (4)	
User entered '1' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:16:28
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:14:39
User opened query 'Please confirm how long 4 mg was taken, as a medrol dose pack is typically tapered for a set amount of days with a set end date/duration. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User closed query 'Please confirm this dosage, as this was a dose pack. Confirm the appropriate dose, duration. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:04:00
Query 'Please confirm this dosage, as this was a dose pack. Confirm the appropriate dose, duration. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:11:35
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:11:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:11:28
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:53:59
User opened query 'Please confirm this dosage, as this was a dose pack. Confirm the appropriate dose, duration. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:53:52
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 19:46:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 19:46:43
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 21:34:42
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:34:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:14:04
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data no required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:27
DataPoint Verified.		12 Nov 2020 16:52:39
User entered 'Other (OTHER)' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:17:27
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:11:28
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:11:28
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:54:01
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:46:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 19:46:43
User entered 'Other (OTHER)' reason for change: Data Entry Error	Cindy Trimmer (b) (4)	12 Oct 2020 19:46:43
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 21:34:42
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:34:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Per DM CLR: Please ensure that tapering doses are reflected as separate entries. Update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please ensure that tapering doses are reflected as separate entries. Update as appropriate.' answered with 'I do not believe this is clinically significant or warranted.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 04:05:00
User opened query 'Per DM CLR: Please ensure that tapering doses are reflected as separate entries. Update as appropriate.'	Anna Gallion (b) (4)	07 Dec 2020 18:01:15
Query answered with 'I do not believe this is clinically significant or warranted.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please ensure that tapering doses are reflected as separate entries. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:40:05
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:14:01
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:29
DataPoint Verified.		12 Nov 2020 16:52:39
User entered 'Participant took standard medrol dose pack. 24 mg day 1, 20 mg day 2, 16 mg day 3, 12 mg day 4, 8 mg day 5, and 4 mg day 6.' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:17:27
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:11:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:11:28
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:54:02
User entered 'Pack' reason for change: Data Entry Error	Cindy Trimmer (b) (4)	12 Oct 2020 19:46:43
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 21:34:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:54
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:32
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		11 Nov 2020 17:14:42
DataPoint Verified.		29 Oct 2020 21:54:04
User entered 'once daily (QD)'		09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:50
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:33
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		11 Nov 2020 17:14:44
DataPoint Verified.		29 Oct 2020 21:54:06
User entered empty.		09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:47
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:35
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		11 Nov 2020 17:14:46
DataPoint Verified.		29 Oct 2020 21:54:07
User entered 'Oral (ORAL)'		09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:43
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:38
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		11 Nov 2020 17:14:48
DataPoint Verified.		29 Oct 2020 21:54:09
User entered empty.		09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:13:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered '08 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:16:28
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:14:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:54:10
User entered '06 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:34:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:25
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Un-verified.		12 Nov 2020 19:27:41
DataPoint Verified.		12 Nov 2020 16:52:39
DataPoint Un-verified.		11 Nov 2020 17:14:51
DataPoint Verified.		29 Oct 2020 21:54:12
User entered '0'		09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:16
User closed query 'Please confirm, as this is a dose pack that typically is tapered from higher dose to lower dose. Please ensure to document each dosage on different lines with start / stop dates.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:12:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
Query 'Please confirm, as this is a dose pack that typically is tapered from higher dose to lower dose. Please ensure to document each dosage on different lines with start / stop dates.' answered with 'updated in source' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:17:57
User entered 'No (N)' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:16:28
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:14:53
User opened query 'Please confirm, as this is a dose pack that typically is tapered from higher dose to lower dose. Please ensure to document each dosage on different lines with start / stop dates.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:05:09
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:54:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:13:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered '13 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:17:27
	(b) (4)	
User entered '12 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:16:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:14:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:54:15
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:13:06
User closed query 'Please confirm, as this was taken for an SAE. Should this be "No"?' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:53:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
Query 'Please confirm, as this was taken for an SAE. Should this be "No"?' answered with 'updated in source.' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:18:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 22:16:28
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:14:55
User opened query 'Please confirm, as this was taken for an SAE. Should this be "No"?' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:04:28
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:54:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '1'	System	09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '1'	System	09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	09 Oct 2020 21:34:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 02:07:18
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 02:07:18
Data point term sent to Coder	System	08 Dec 2020 15:11:06
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:10:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:46
Data point term sent to Coder	System	13 Nov 2020 21:43:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:01

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:14:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:14:51
Data point term sent to Coder	System	29 Oct 2020 20:57:58
User entered 'Meclizine'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:02
User entered 'Yes (Y)'	Clarence Creech (b) (4)	29 Oct 2020 20:57:13
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:10:17
User entered 'NAUSEA PREVENTION, post operative care' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:10:17
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:04
User entered 'Nausea Prevention'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:05
User entered '25'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:07
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 20:57:13
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:08
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 20:57:13
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:11
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:12
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:14
User entered 'Oral (ORAL)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:16
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 20:57:13
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:19
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 20:57:13
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:21
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 20:57:13
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:23
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 20:57:13
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:25
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:26
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 20:57:13

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: ANTISEPTICS, PRODUCT: POVIDONE-IODINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Dec 2020 00:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:45:44
Data point term sent to Coder	System	08 Dec 2020 15:11:05
Coding entries removed.	Anna Gallion (b) (4)	08 Dec 2020 15:10:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: ANTISEPTICS, PRODUCT: POVIDONE-IODINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Nov 2020 06:48:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:48:48
Data point term sent to Coder	System	13 Nov 2020 21:43:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:49
Data point term sent to Coder	System	29 Oct 2020 20:59:01
User entered 'Povidone iodine topical'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:50
User entered 'Yes (Y)'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:10:27
User entered 'POST-OPERATIVE CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:10:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:51
User entered 'Post-operative care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:53
User entered 'I'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:55
User entered 'Other (OTHER)'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:56
User entered 'topical application'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:57
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:59
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:15:02
User entered 'Nasal (NASAL)'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:15:03
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:15:05
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:15:07
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:15:08
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:15:10
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:15:11
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 20:58:57
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:14:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 20:58:57

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 15:20:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 15:20:01
Data point term sent to Coder	System	08 Dec 2020 15:11:05
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:10:37
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)	13 Nov 2020 21:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:59:47
Data point term sent to Coder	System	13 Nov 2020 21:43:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Verified.		11 Nov 2020 18:22:46

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
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)	30 Oct 2020 04:50:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:50:47
Data point term sent to Coder	System	29 Oct 2020 21:02:05
User entered 'acetaminophen-hydrocodone (325/5 mg)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:44
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:01:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:48:16
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:25:12
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:10:37
User entered 'PAIN CONTROL, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:10:37
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:03:41
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:04:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:43
User entered 'Pain Control'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:41
User entered 'I'	Clarence Creech (b) (4)	29 Oct 2020 21:01:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:40
User entered 'tablet (TABLET)'	Clarence Creech (b) (4)	29 Oct 2020 21:01:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:38
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:36
User entered 'as needed (PRN)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:34
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:01:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:33
User entered 'Oral (ORAL)'	Clarence Creech (b) (4)	29 Oct 2020 21:01:51
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:32
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:30
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:29
User entered '0'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:27
User entered 'No (N)' reason for change: New Information	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:02:11
User entered 'Yes (Y)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:26
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	29 Oct 2020 21:02:23
User entered '06 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:02:23
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	29 Oct 2020 21:02:11
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:22:24
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:20
DataPoint activated with code reason code Data required.		13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:01:51

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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)	10 Dec 2020 18:58:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 18:58:52
Data point term sent to Coder Coding entries removed.	System Anna Gallion (b) (4)	08 Dec 2020 15:11:05 08 Dec 2020 15:10:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:49
Data point term sent to Coder	System	13 Nov 2020 21:43:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:18
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)	29 Oct 2020 21:16:46

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'cefazolin'	Coder Import (b) (4) (b) (4) System Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:16:46 29 Oct 2020 21:07:11 29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:20
User entered 'Yes (Y)'	Clarence Creech (b) (4)	29 Oct 2020 21:07:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:24
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:10:51
User entered 'SURGICAL PROPHYLAXIS, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:10:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:21
User entered 'Surgical Prophylaxis'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:23
User entered '2'	Clarence Creech (b) (4)	29 Oct 2020 21:07:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:41
User entered 'g (g)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:42
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:44
User entered 'other (OTHER)'	Clarence Creech (b) (4)	29 Oct 2020 21:07:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:46
User entered 'Twice'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:47
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:49
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:50
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:07:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:52
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:07:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:54
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Please confirm, end date seems to be noted as 07Oct2020. If confirmed, please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:38:28
Query 'Please confirm, end date seems to be noted as 07Oct2020. If confirmed, please update or clarify otherwise.' answered with 'Updated per source.' (Site from CRA).	Clarence Creech (b) (4)	11 Nov 2020 22:00:59
User entered '07 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:00:44
User opened query 'Please confirm, end date seems to be noted as 07Oct2020. If confirmed, please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:52:14
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:52:58
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:07:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 20:32:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 20:32:01
Data point term sent to Coder	System	08 Dec 2020 15:11:06
Coding entries removed.	Anna Gallion (b) (4)	08 Dec 2020 15:11:01
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLYCOPYRRONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:59:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:59:48
Data point term sent to Coder	System	13 Nov 2020 21:43:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:28
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLYCOPYRRONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 00:33:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 00:33:53
Data point term sent to Coder	System	29 Oct 2020 21:09:14

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Glycopyrrolate'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:26
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:25:23
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:11:01
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:11:01
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:04:01
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:28:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:25
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:24
User entered '0.4'	Clarence Creech (b) (4)	29 Oct 2020 21:08:58
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:22
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:08:58
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:21
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:19
User entered 'once (ONCE)'	Clarence Creech (b) (4)	29 Oct 2020 21:08:58
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:18
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:16
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:15
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:13
User entered '6 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:08:58
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:11
User entered '0'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:09
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:08:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:08
User entered '6 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:08:58
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:07
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:08:58
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:08:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: PARASYMPATHOMIMETICS, ATC: ANTICHOLINESTERASES, PRODUCT: NEOSTIGMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 18:21:48
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 18:21:48
Data point term sent to Coder	System	08 Dec 2020 15:12:07
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:11:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: PARASYMPATHOMIMETICS, ATC: ANTICHOLINESTERASES, PRODUCT: NEOSTIGMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:46
Data point term sent to Coder	System	13 Nov 2020 21:43:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: PARASYMPATHOMIMETICS, ATC: ANTICHOLINESTERASES, PRODUCT: NEOSTIGMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:27:48
Data point term sent to Coder	System	29 Oct 2020 21:10:15

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'neostigmine'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:44
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:25:28
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:11:15
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:11:15
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:04:07
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:44:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:46
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:48
User entered '3'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:50
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:53
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:54
User entered 'once (ONCE)'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:55
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:45:59
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:00
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:21
User entered '6 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:23
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:26
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:27
User entered '6 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:29
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:09:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:09:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Dec 2020 00:07:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 00:07:56
Data point term sent to Coder	System	08 Dec 2020 15:12:06
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:11:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:47
Data point term sent to Coder	System	13 Nov 2020 21:43:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:33:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:33:45
Data point term sent to Coder	System	29 Oct 2020 21:11:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'clonidine'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:43
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:11:30
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:11:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:44
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:46
User entered '50'	Clarence Creech (b) (4)	29 Oct 2020 21:10:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:31:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Verified.		11 Nov 2020 19:46:49
Query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' answered with 'updated' (Site from DM).		09 Nov 2020 19:13:57
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:13:45
User opened query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:32:57
User entered 'Other (OTHER)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:13:45
User entered 'mcg'	Clarence Creech (b) (4)	29 Oct 2020 21:10:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:53
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:46:55
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:10:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:47:16
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:47:17
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:47:29
User entered '6 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:47:31
User entered '0'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:47:32
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:10:26
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:47:33
User entered '6 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:47:35
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:10:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 10:07:40
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 10:07:40
Data point term sent to Coder Coding entries removed.	System Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:12:07 08 Dec 2020 15:11:44
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)	13 Nov 2020 21:44:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:48
Data point term sent to Coder	System	13 Nov 2020 21:43:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:52:51
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)	30 Oct 2020 05:28:49

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'ondansetron'	Coder Import (b) (4) (b) (4) System Clarence Creech (b) (4) (b) (4)	30 Oct 2020 05:28:49 29 Oct 2020 21:11:18 29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:52:54
User entered 'Yes (Y)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:06
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:25:37
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:11:44
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:11:44
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:04:18
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:45:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:52:55
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:52:59
User entered '4'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:53:00
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:06
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:53:02
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:53:04
User entered 'once (ONCE)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:06
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:48
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:50
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:57
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:58
User entered '6 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:11:06
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:00
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:11:06
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:01
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:06
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:03
User entered '6 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:04
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:11:06

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Dec 2020 20:49:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:49:46
Data point term sent to Coder	System	08 Dec 2020 15:12:07
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:11:55
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)	13 Nov 2020 21:44:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:45
Data point term sent to Coder	System	13 Nov 2020 21:43:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:16
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)	30 Oct 2020 05:31:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'phenylephrine'	Coder Import (b) (4) (b) (4) System Clarence Creech (b) (4) (b) (4)	30 Oct 2020 05:31:00 29 Oct 2020 21:12:19 29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:17
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:11:55
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:11:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:19
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:20
User entered '100'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:22
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:14:46
User entered 'Other (OTHER)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:32:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.		13 Nov 2020 21:42:53
DataPoint Verified.		11 Nov 2020 19:11:24
Query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' answered with 'updated' (Site from DM).		09 Nov 2020 19:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 19:14:46
User opened query 'Per CDM: 'Dose Unit' is 'Other' and 'If dose unit is Other, specify' is entered as 'MCG'. Please review predefined options available for 'Dose Unit' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:33:14
User entered 'mcg'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:26
User entered 'as needed (PRN)' reason for change:	Clarence Creech (b) (4)	29 Oct 2020 21:13:12
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:27
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:29
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:30
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:32
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:33
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:35
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:36
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:11:38
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:11:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:11:44

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 13:15:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 13:15:12
Data point term sent to Coder	System	08 Dec 2020 15:13:08
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:12:10
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) (b) (4)	13 Nov 2020 22:15:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 22:15:49
Data point term sent to Coder	System	13 Nov 2020 21:43:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:47:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:47:50
Data point term sent to Coder	System	29 Oct 2020 21:13:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Propofol'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:11
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:25:56
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:12:10
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:12:10
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:04:27
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:49:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:10
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:08
User entered '244.125'	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:06
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:04
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:03
User entered 'once (ONCE)'	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:01
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:00
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:56
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:54
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:52
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:51
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:12:36
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:47
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:46
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:12:36

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 23:19:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 23:19:52
Data point term sent to Coder	System	08 Dec 2020 15:13:08
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:12:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:49
Data point term sent to Coder	System	13 Nov 2020 21:43:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:05:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:05:55
Data point term sent to Coder	System	29 Oct 2020 21:14:22

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ketamine'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:47
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:26:01
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:12:20
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:12:20
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:04:33
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:35:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:49
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:50
User entered '20'	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:52
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:53
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:55
User entered 'as needed (PRN)' reason for change:	Clarence Creech (b) (4)	29 Oct 2020 21:15:11
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:56
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:58
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:02:59
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:01
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:03
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:04
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:07
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:06
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:07
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:14:07

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:14:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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)	11 Dec 2020 13:06:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 13:06:33
Data point term sent to Coder Coding entries removed.	System Anna Gallion (b) (4)	08 Dec 2020 15:14:10 08 Dec 2020 15:13:29
Data point term sent to Coder DataPoint activated with code reason code Data required.	System Anna Gallion (b) (4)	08 Dec 2020 15:13:09 08 Dec 2020 15:13:03
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System Anna Gallion (b) (4)	08 Dec 2020 15:05:55 08 Dec 2020 15:05:29
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)	13 Nov 2020 21:59:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 21:59:49
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	13 Nov 2020 21:43:41 13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:18

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
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)	30 Oct 2020 05:50:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:50:49
Data point term sent to Coder	System	29 Oct 2020 21:15:29
User entered 'rocuronium'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	11 Nov 2020 20:03:19
User entered 'No (N)'	Clarence Creech (b) (4)	
	(b) (4)	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:26:05
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:13:29
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:13:29
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	(b) (4)	08 Dec 2020 15:04:41
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:59:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:21
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:22
User entered '10'	Clarence Creech (b) (4)	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:24
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:58
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:25
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:27
User entered 'as needed (PRN)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:28
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:14:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:30
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:31
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:14:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	11 Nov 2020 20:03:33
User entered '06 Oct 2020'	Clarence Creech (b) (4)	
	(b) (4)	29 Oct 2020 21:14:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:35
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:14:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:36
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	11 Nov 2020 20:03:38
User entered '06 Oct 2020'	Clarence Creech (b) (4)	
	(b) (4)	29 Oct 2020 21:14:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:40
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:14:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:58
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 15:13:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Dec 2020 15:05:29
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:14:58

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Per CDM re-query: Per previous query, please review the start/stop date of this medication as it overlaps with Con Med name, # 29 ROCORONIUM / (06Oct2020-06Oct2020). Please update the dates else review if this is a duplicate. Please update as appropriate else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 08:49:01
Query 'Per CDM re-query: Per previous query, please review the start/stop date of this medication as it overlaps with Con Med name, # 29 ROCORONIUM / (06Oct2020-06Oct2020). Please update the dates else review if this is a duplicate. Please update as appropriate else clarify.' answered with 'PARTICIPANT RECIEVED TWO INJECTIONS ON SAME DAY' (Site from DM).	April Hanlotxomphou (b) (4)	17 Dec 2020 16:11:13
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 29 ROCORONIUM / (06Oct2020-06Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:30:39
User opened query 'Per CDM re-query: Per previous query, please review the start/stop date of this medication as it overlaps with Con Med name, # 29 ROCORONIUM / (06Oct2020-06Oct2020). Please update the dates else review if this is a duplicate. Please update as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:30:36
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)	11 Dec 2020 13:06:33

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Anna Gallion (b) (4) (b) (4)	11 Dec 2020 13:06:33 08 Dec 2020 15:13:08 08 Dec 2020 15:12:37
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 29 ROCORONIUM / (06Oct2020-06Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication. ' (Site from DM).	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:04:52
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 29 ROCORONIUM / (06Oct2020-06Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 22:00:09
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)	13 Nov 2020 21:59:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder DataPoint activated with code reason code Data required.	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	13 Nov 2020 21:59:50 13 Nov 2020 21:43:40 13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:50

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
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)	30 Oct 2020 05:50:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:50:49
Data point term sent to Coder	System	29 Oct 2020 21:16:30
User entered 'rocuronium'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:16:15

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:52
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:26:12
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:12:37
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:12:37
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate. ' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication. ' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:04:55
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 22:00:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:56
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:16:15

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:58
User entered '50'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:00
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:02
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:04
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:16:15

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:06
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:07
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:09
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:11
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:13
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:15
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:16
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:16:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:05:18
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:16:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:16:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:16:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:16:15

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 23:54:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 23:54:46
Data point term sent to Coder	System	08 Dec 2020 15:14:10
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:13:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:45
Data point term sent to Coder	System	13 Nov 2020 21:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:15

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

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: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:06:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:06:48
Data point term sent to Coder	System	29 Oct 2020 21:30:43
User entered 'ketorolac' reason for change: Data Entry Error	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:30:31
Data point term sent to Coder	System	29 Oct 2020 21:17:32
User entered 'methocarbamol'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:18
User entered 'Yes (Y)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:31:24
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:13:44
User entered 'PAIN CONTROL, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:13:44
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:05:01
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:35:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:20
User entered 'Pain Control'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:21
User entered '15'	Clarence Creech (b) (4)	29 Oct 2020 21:17:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:24
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:17:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:25
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:17:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:27
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:32
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:33
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:35
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:44
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:17:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:45
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:17:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:47
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:17:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:48
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:06:50
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:17:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Dec 2020 14:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:57:45
Data point term sent to Coder	System	08 Dec 2020 15:15:12
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:14:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:47
Data point term sent to Coder	System	13 Nov 2020 21:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:19:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:19:49
Data point term sent to Coder	System	29 Oct 2020 21:29:42

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'midazolam'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:18
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:31:29
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:14:23
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:14:23
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:05:09
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:40:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:19
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:22
User entered '2'	Clarence Creech (b) (4)	29 Oct 2020 21:29:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:24
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:29:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:26
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:28
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:29
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:30
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:32
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:35
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:29:34
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:36
User entered '0'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:37
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:39
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:10:40
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:29:34

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:50
Data point term sent to Coder	System	13 Nov 2020 21:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:59:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 11:59:52
Data point term sent to Coder	System	29 Oct 2020 21:33:53
User entered 'ibuprofen'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:58
User entered 'Yes (Y)'	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:56
User entered 'pain prevention'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:55
User entered '400'	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:53
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:51
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:50
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:48
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:47
User entered 'Oral (ORAL)'	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:46
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:42
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:41
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:33:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:39
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:38
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:11:36
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:33:42

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 16:10:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 16:10:44
Data point term sent to Coder Coding entries removed.	System Anna Gallion (b) (4)	08 Dec 2020 15:17:13 08 Dec 2020 15:16:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 21:44:44
Data point term sent to Coder	System	13 Nov 2020 21:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 05:18:53

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'methocarbamol'	Coder Import (b) (4) (b) (4) System Clarence Creech (b) (4) (b) (4)	30 Oct 2020 05:18:53 29 Oct 2020 21:31:44 29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:27
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:31:36
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:16:48
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:16:48
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:05:42
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:40:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:28
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:41
User entered 'I'	Clarence Creech (b) (4)	29 Oct 2020 21:31:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:43
User entered 'g (g)'	Clarence Creech (b) (4)	29 Oct 2020 21:31:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:44
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:45
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:47
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:48
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:50
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:31:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:51
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:53
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:31:03
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:54
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:55
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:26:57
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:31:03

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 00:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:55:46
Data point term sent to Coder	System	08 Dec 2020 15:17:13
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:16:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:44
Data point term sent to Coder	System	13 Nov 2020 21:43:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:11:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:11:57
Data point term sent to Coder	System	29 Oct 2020 21:31:44
User entered 'lidocaine'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:57
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:31:41
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:16:59
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:16:59
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:05:47
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:37:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:58
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:00
User entered '70'	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:02
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:03
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:04
User entered 'once (ONCE)'	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:06
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:07
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:09
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:10
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:16
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:18
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:19
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:23
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:31:38
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:31:38

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 13:15:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 13:15:12
Data point term sent to Coder	System	08 Dec 2020 15:10:04
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:09:10
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) (b) (4)	13 Nov 2020 21:44:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:43
Data point term sent to Coder	System	13 Nov 2020 21:43:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:47:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:47:51
Data point term sent to Coder	System	29 Oct 2020 21:32:51

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'propofol'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:48
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:31:50
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:09:10
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:09:10
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:05:54
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:50:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:50
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:51
User entered '200'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:53
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:56
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:58
User entered 'once (ONCE)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:00
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:01
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:02
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:04
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:06
User entered '0'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:08
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:09
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:11
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:32:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:32:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:32:09

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Dec 2020 00:13:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 00:13:53
Data point term sent to Coder Coding entries removed.	System Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:09:01 08 Dec 2020 15:08:57
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)	13 Nov 2020 21:44:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:45
Data point term sent to Coder	System	13 Nov 2020 21:43:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 00:18:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 00:18:45
Data point term sent to Coder	System	29 Oct 2020 21:32:52
User entered 'dexamethasone'	Clarence Creech (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:38
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:31:55
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:08:57
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:08:57
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:05:59
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:23:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:40
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:42
User entered '10'	Clarence Creech (b) (4)	29 Oct 2020 21:32:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:44
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:46
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:50
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:54
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:56
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:58
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:04
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:32:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:06
User entered '0'	Clarence Creech (b) (4)	29 Oct 2020 21:32:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:08
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:32:41
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:10
User entered '06 Oct 2020'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:12
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:32:41

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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.	(b) (4) Coder Import (b) (4)	10 Dec 2020 19:08:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:08:52
Data point term sent to Coder	System	08 Dec 2020 15:09:01
Coding entries removed.	Anna Gallion (b) (4)	08 Dec 2020 15:08:48
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.	(b) (4) Coder Import (b) (4)	13 Nov 2020 22:15:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 22:15:49
Data point term sent to Coder	System	13 Nov 2020 21:43:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:26

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
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)	30 Oct 2020 00:25:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 00:25:46
Data point term sent to Coder	System	29 Oct 2020 21:34:55
User entered 'famotidine'	Clarence Creech (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:28
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:34:23
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:31:59
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:08:48
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:08:48
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:06:04
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:24:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:29
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:32
User entered '20'	Clarence Creech (b) (4)	29 Oct 2020 21:34:23
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:33
User entered 'mg (mg)'	Clarence Creech (b) (4)	29 Oct 2020 21:34:23
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:36
User entered empty.	Clarence Creech (b) (4)	29 Oct 2020 21:34:23
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:38
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:39
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:40
User entered 'Oral (ORAL)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:42
User entered empty.	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:43
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:34:23
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:45
User entered '0'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:47
User entered 'No (N)'	Clarence Creech (b) (4) (b) (4)	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:48
User entered '06 Oct 2020'	Clarence Creech (b) (4)	29 Oct 2020 21:34:23
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:30:50
User entered 'No (N)'	Clarence Creech (b) (4)	29 Oct 2020 21:34:23
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	29 Oct 2020 21:34:23

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:57:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, PRODUCT: ANESTHETICS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:07:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:07:13
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	01 Apr 2021 23:11:59
Data point term sent to Coder	System	26 Jan 2021 16:58:46
DataPoint Un-verified.	Anna Gallion (b) (4) (b) (4)	26 Jan 2021 16:58:05
User entered 'BKK [Bupivacaine, Ketorolac and Ketamine]' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	26 Jan 2021 16:58:05
Data point term sent to Coder	System	26 Jan 2021 16:57:43
User closed query 'Requery: CDM-Coding: Please UPDATE the eCRF to include the active ingredient name(s) in brackets next to the drug' (Site from System).	System	26 Jan 2021 16:57:24
Query 'Requery: CDM-Coding: Please UPDATE the eCRF to include the active ingredient name(s) in brackets next to the drug' answered with 'I really think it is not clinically significant. But I will include in brackets if that is really what you need. Thanks.' (Site from System).	Anna Gallion (b) (4) (b) (4)	26 Jan 2021 16:57:24
User opened query 'Requery: 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) (b) (4)	28 Dec 2020 17:25:22
Data point term sent to Coder	System	02 Dec 2020 20:58:54
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	02 Dec 2020 20:58:40
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'Bupivacaine, Ketorolac and Ketamine' (Site from System).	Anna Gallion (b) (4) (b) (4)	02 Dec 2020 20:58:40

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 10:02:08
Data point term sent to Coder	(b) (4)	
DataPoint activated with code reason code Data required.	System	13 Nov 2020 21:43:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
	(b) (4), (b) (6)	12 Nov 2020 16:47:10
Data point term sent to Coder	System	11 Nov 2020 22:04:06
User entered 'BKK'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:11
User entered 'No (N)'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:13
User entered 'Spinal Stenosis Repair'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than mL. Please verify the dose and unit, and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 07:02:48
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than mL. Please verify the dose and unit, and update as appropriate.' answered with 'DOSES UNAVAILABLE, INFORMATION FROM PROCEDURE RECORD AND DOSING NOT SPECIFIC FOR EACH COMPONENT.' (Site from DM).	April Hanlotxomphou (b) (4)	08 Mar 2021 20:42:49
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than mL. Please verify the dose and unit, and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 00:58:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:17
User entered '55'	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:03:29

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:20
User entered 'mL (mL)'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:23
User entered empty.	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:27
User entered 'once (ONCE)'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:30
User entered empty.	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:03:15
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. Otherwise, provide clarification. ' answered with 'PER PROCEDURE RECORD, ROUTE IS SQ' (Site from DM).	April Hanlotxomphou (b) (4)	08 Mar 2021 20:43:23
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 00:58:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:34
User entered empty.	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:36
User entered '06 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4)	11 Nov 2020 22:05:45
User entered '06 Nov 2020'	(b) (4)	
	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:38
User entered '0'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:40
User entered 'No (N)'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:41
User entered '06 Oct 2020' reason for change: Data Entry Error	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:05:45
User entered '06 Nov 2020'	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:03:29

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:43
User entered 'No (N)'	Clarence Creech (b) (4)	11 Nov 2020 22:03:29
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	11 Nov 2020 22:03:29

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	11 Nov 2020 22:03:29

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	11 Nov 2020 22:03:29

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 15:15:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 15:15:02
Data point term sent to Coder	System	08 Dec 2020 15:09:00
Coding entries removed.	Anna Gallion (b) (4)	08 Dec 2020 15:08:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 21:59:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 21:59:49
Data point term sent to Coder	System	13 Nov 2020 21:43:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Nov 2020 00:10:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Albumin Human'	Coder Import (b) (4) (b) (4) System Clarence Creech (b) (4) (b) (4)	12 Nov 2020 00:10:38 11 Nov 2020 22:06:09 11 Nov 2020 22:05:27

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'No (N)'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:32:12
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 15:08:10
User entered 'SURGICAL CARE, SPINAL STENOSIS REPAIR' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 15:08:10
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication.' (Site from DM).	Anna Gallion (b) (4)	08 Dec 2020 15:06:32
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:07:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'Surgical Care'	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:05:27

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered '12.5'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'g (g)'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered empty.	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'once (ONCE)'	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:05:27

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered empty.	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'Intravenous (INTRAVENOUS)'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered empty.	Clarence Creech (b) (4) (b) (4)	11 Nov 2020 22:05:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered '06 Oct 2020'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered '0'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'No (N)'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered '06 Oct 2020'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:52:39
User entered 'No (N)'	Clarence Creech (b) (4)	11 Nov 2020 22:05:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	11 Nov 2020 22:05:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	11 Nov 2020 22:05:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered empty.	System	11 Nov 2020 22:05:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 07:31:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 07:31:00
Data point term sent to Coder	System	01 Feb 2021 19:15:39
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	01 Feb 2021 19:14:58
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)	13 Nov 2020 21:59:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:59:48
Data point term sent to Coder	System	13 Nov 2020 21:43:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
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)	12 Nov 2020 19:41:50

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	12 Nov 2020 19:41:50 12 Nov 2020 19:25:52
Data point term sent to Coder	System	12 Nov 2020 19:10:36
Data point term sent to Coder	System	12 Nov 2020 19:08:32
User entered 'acetaminophen-hydrocodone'	(b) (4), (b) (6) 	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:46:42
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).	(b) (4), (b) (6)	04 Feb 2021 13:02:43
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 'post operative pain control.' (Site from DM).	Anna Gallion (b) (4) (b) (4)	01 Feb 2021 19:15:13
DataPoint Un-verified.	Anna Gallion (b) (4) (b) (4)	01 Feb 2021 19:14:58
User entered 'Post operative pain control' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	01 Feb 2021 19:14:58
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)	01 Feb 2021 07:34:46
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:50:36
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication. ' (Site from DM).	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:06:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:04:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:56
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:10:16
User entered 'pain control' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:57
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:10:16
User entered '325/10' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:54
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 23:44:18
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:07:35
DataPoint Un-verified.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:07:13
User entered 'mg (mg)' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:07:13
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:04:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:59
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:10:16
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:02
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:10:16
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:04
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:05
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:10:16
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:11
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:09
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Nov 2020 19:10:16
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:13
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 19:08:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:18
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:10:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:20
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:23
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:10:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:10:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:10:16
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:08:16
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:08:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '1'	System	12 Nov 2020 19:10:16
User entered empty.	System	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '1'	System	12 Nov 2020 19:10:16
User entered empty.	System	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	12 Nov 2020 19:10:16
User entered empty.	System	12 Nov 2020 19:08:16

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:44:48
Data point term sent to Coder	System	13 Nov 2020 21:43:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
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)	12 Nov 2020 19:41:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 19:41:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:26
Data point term sent to Coder	System	12 Nov 2020 19:12:38
User entered 'acetaminophen-hydrocodone'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:28
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 05:50:25
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' answered with 'Per PI, this should not be required as this was given in patient while patient had a surgery. We cannot supply indication. ' (Site from DM).	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 15:06:52
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:04:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:29
User entered 'pain control'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:32
User entered '325/7.5'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:34
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:37
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:39
User entered 'four times daily (QID)'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:41
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:47
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:49
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:51
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:54
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint activated with code reason code Data required.	(b) (4)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:26:56
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '4'	System	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '1'	System	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:45:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 21:43:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 21:42:53
User entered '804 (804)'	System	12 Nov 2020 19:12:00

US3422135

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:33:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:21
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:01:07
User entered 'Yes (Y)' reason for change: New Information	Cindy Trimmer (b) (4)	12 Oct 2020 19:47:04
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	28 Aug 2020 15:46:39

US3422135

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:17

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:22:45
User entered '06 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	12 Oct 2020 19:47:23

US3422135

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:17

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:24:15
	(b) (4), (b) (6)	11 Nov 2020 21:22:47
User closed query 'Please confirm if the surgical procedure term should be decompressive lumbar laminectomy and fusion. With transforaminal lateral interbody fusion L4-5' (Site from CRA).		
Query 'Please confirm if the surgical procedure term should be decompressive lumbar laminectomy and fusion. With transforaminal lateral interbody fusion L4-5' answered with 'corrected' (Site from CRA).	Naomi Kown (b) (4)	27 Oct 2020 18:19:47
	(b) (4)	
User entered 'laminectomy with posterolateral fusion' reason for change: Data Entry Error	Naomi Kown (b) (4)	27 Oct 2020 18:18:58
	(b) (4)	
User opened query 'Please confirm if the surgical procedure term should be decompressive lumbar laminectomy and fusion. With transforaminal lateral interbody fusion L4-5' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 17:49:00
User entered 'Lumber spine fusion'	Cindy Trimmer (b) (4)	12 Oct 2020 19:47:23
	(b) (4)	

US3422135

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:22:49
User entered 'Medical History (MH)'	Cindy Trimmer (b) (4) (b) (4)	12 Oct 2020 19:47:23

US3422135

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:33:17

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:22:50
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	12 Oct 2020 19:47:23

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered	System	12 Oct 2020 15:05:43
'USA-US082-2020-MRNA-1273-P301000001'		

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:18
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Clarence'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Creech'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'CCC-5311 MCN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Nashville'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'TN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered '37027'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:28
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:28:56
User entered 'US'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:34:53
User entered '3'	System	23 Oct 2020 19:25:53
User entered '2'	System	13 Oct 2020 14:29:04
User entered '1'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered	System	12 Oct 2020 15:05:43
'USA-US082-2020-MRNA-1273-P301000001'		

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:18
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Clarence'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Creech'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'CCC-5311 MCN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Nashville'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'TN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered '37027'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:28
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:28:56
User entered 'US'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:34:53
User entered '3'	System	23 Oct 2020 19:25:53
User entered '2'	System	13 Oct 2020 14:29:04
User entered '1'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:33:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:43
User entered '12/Oct/2020 11:06'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:33:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:28:56
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'USA-US082-2020-MRNA-1273-P301000001'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:18
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Clarence'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Creech'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'CCC-5311 MCN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Nashville'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'TN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered '37027'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:28
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:28:56
User entered 'US'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:34:53
User entered '3'	System	23 Oct 2020 19:25:53
User entered '2'	System	13 Oct 2020 14:29:04
User entered '1'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:33:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:03
User entered '13/Oct/2020 10:29'	System	13 Oct 2020 14:29:04

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:33:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 19:25:34
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 14:29:04

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'USA-US082-2020-MRNA-1273-P301000001'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:18
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Clarence'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Creech'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'CCC-5311 MCN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Nashville'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'TN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered '37027'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:28
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:28:56
User entered 'US'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:34:53
User entered '3'	System	23 Oct 2020 19:25:53
User entered '2'	System	13 Oct 2020 14:29:04
User entered '1'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:33:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:16
User entered '23/Oct/2020 19:25'	System	23 Oct 2020 19:25:53

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:33:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:16:18
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 19:26:00
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 19:25:53

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'USA-US082-2020-MRNA-1273-P301000001'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Yes (Y)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:18
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'No (N)'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Clarence'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Creech'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'CCC-5311 MCN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'Nashville'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered 'TN'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:06:56
User entered '37027'	System	12 Oct 2020 15:05:43

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:15:28
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:28:56
User entered 'US'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:34:53
User entered '3'	System	23 Oct 2020 19:25:53
User entered '2'	System	13 Oct 2020 14:29:04
User entered '1'	System	12 Oct 2020 15:07:00

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:33:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:16:22
User entered '30/Oct/2020 10:34'	System	30 Oct 2020 14:34:53

US3422135

Folder: SAE USA-US082-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:33:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:11:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:16:23
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 14:34:53